

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS )  
CORPORATION, )  
Plaintiff, ) Redacted - Public Version  
v. )  
LIQUIDIA TECHNOLOGIES, INC., ) C.A. No. 23-975-RGA-SRF  
Defendant. ) [REDACTED]

**RESPONSIVE LETTER TO THE HONORABLE SHERRY R. FALLON FROM  
NATHAN R. HOESCHEN REGARDING DISCOVERY DISPUTE**

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Dated: January 22, 2025

January 22, 2025

**BY CM/ECF & HAND DELIVERY**

The Honorable Sherry R. Fallon  
United States District Court  
844 N. King Street  
Wilmington, DE 19801

Re: *United Therapeutics Corp. v. Liquidia Technologies, Inc.* C.A. No. 23-975-RGA-SRF

Dear Judge Fallon,

The Court should deny UTC's motion to strike certain of Liquidia's discovery disclosures. UTC's letter brands Liquidia's contentions as "new" but makes no attempt to explain how the listed theories are "new" or not previously known to UTC. Liquidia met the October 30 contention deadline, but significant discovery took place after October 30—discovery that UTC's letter ignores—and Liquidia supplemented its contentions to account for it. Finally, this dispute is a problem of UTC's own making, arising solely from UTC's unwillingness to meaningfully meet and confer regarding supplementation of the parties' final contentions.

**I. FACTUAL BACKGROUND**

UTC disregards that numerous key depositions—including the inventors—occurred after Oct. 30: Victor Tapson (Nov. 5), Leigh Peterson (Nov. 6), Kevin Laliberte (Nov. 8), Gregory Bottorff (Nov. 12), CQ Deng (Nov. 12), Peter Smith (Nov. 13), Shaun Snader (Nov. 26), and Dr. Waxman (Dec. 12).<sup>1</sup> During an Oct. 23 meet-and-confer, Liquidia proposed extending the deadline for the parties' final contentions through at least the close of fact discovery. *See Ex. 1.* UTC contends that Liquidia "never followed through" (D.I. 241 at 1), but UTC stated on Oct. 23 that it would consider that proposal. Instead, UTC sandbagged Liquidia with service of its final infringement contentions on October 30. *See Ex. 1.* Two days later, without explanation, UTC informed Liquidia that it would not agree to an extension for the contentions. *See id.* at 1. Now, UTC seeks to use its delayed depositions and belated rejection to disadvantage Liquidia.

**II. LEGAL STANDARD AND ANALYSIS**

Liquidia does not seek to modify the scheduling order as it complied with the Court's Oct. 30 deadline, and then supplemented its contentions to provide more specificity based on information obtained after Oct. 30. Thus, the "good cause" standard does not apply.<sup>2</sup> The following *Pennypack* factors, which UTC ignores, govern the exclusion of evidence and whether a disclosure is "substantially justified" or "harmless" under Rule 37, provide the proper framework for this dispute: "(1) the importance of the information withheld; (2) the prejudice or surprise to the party

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<sup>1</sup> UTC knowingly offered these depositions after the Oct. 30 deadline for final contentions. *See Ex. 10 at 1-2* (offering Peterson, Bottorff, Deng, Smith, Tapson, and Laliberte).

<sup>2</sup> The cases cited by UTC are inapplicable to the facts here because (1) the defendant in *Chevron* supplemented its invalidity contentions nearly *two years* after court-ordered deadline, and (2) the plaintiff in *Vaxcel* did not file *any* contentions by the court-ordered deadline. *Chevron (HK) Ltd. v. One World Techs., Inc.*, 2023 WL 2372938, at \*3 (D. Del. Mar. 6, 2023); Ex. H.

against whom the evidence is offered; (3) the likelihood of disruption of the trial; (4) the possibility of curing the prejudice; (5) the explanation for the failure to disclose; and (6) the presence of bad faith or willfulness in not disclosing the evidence.” *B. Braun Melsungen AG v. Terumo Med. Corp.*, 749 F. Supp. 2d 210, 221 (D. Del. 2010) (citing *Meyers v. Pennypack Woods Home Ownership Assn.*, 559 F.2d 894, 904-05 (3d Cir. 1977)). “The exclusion of critical evidence is an ‘extreme’ sanction, not normally to be imposed absent a showing of willful deception or ‘flagrant disregard’ of a court order by the proponent of the evidence.” *Pennypack*, 559 F.2d at 905 (quotation removed); *see also ABB Air Preheater, Inc. v. Regenerative Envtl. Equip. Co.*, 167 F.R.D. 668, 671 (D.N.J. 1996) (“Courts in the Third Circuit should exercise particular restraint in considering motions to exclude evidence.”).

#### A. Factor No. 1 (importance of the information)

“In weighing this factor, this Court has previously explained that: ‘[c]ourts favor the resolution of disputes on their merits.’” *Withrow v. Spears*, 967 F. Supp. 2d 982, 1005 (D. Del. Aug. 22, 2013) (quotation removed). The identified portions of Liquidia’s contentions UTC seeks to strike are important to Liquidia’s case, as they provide Liquidia’s invalidity positions.

#### B. Factor Nos. 2 (prejudice or surprise) and 4 (possibility of curing prejudice)

“The purpose of contention interrogatories . . . is to give each party sufficient notice of the opposing party’s contentions at trial and an opportunity to respond to those contentions.” *Thorn EMI N. Am. v. Intel Corp.*, 936 F. Supp. 1186, 1191 (D. Del. 1996); *see also Boehringer Ingelheim Int’l GMBH v. Barr Labs. Inc.*, 2008 U.S. Dist. LEXIS 53475, at \*5 (D. Del. July 15, 2008) (finding plaintiff on notice of contentions because, *inter alia*, “documents filed in this case reveal Defendants’ contentions, including [] interrogatory responses”); *cf. Finjan, Inc. v. Rapid7, Inc.*, 2020 WL 5798545, at \*1-6 (D. Del. Sept. 29, 2020) (striking new legal theories presented in an expert report). By Oct. 30, and even earlier, Liquidia provided UTC with adequate notice, such that there is no prejudice or surprise:

1. **Improper Inventorship** (Ex. A, § II.C). Liquidia disclosed this contention on Oct. 30: “Liquidia anticipates further supplementation of its invalidity and unenforceability positions including at least the following: . . . improper inventorship of the ’327 patent[.]” Ex. 2 at 2. The Dec. 3 contentions included highly relevant testimony from Dr. Smith on Nov. 13, regarding [REDACTED]

[REDACTED] . See Ex. 3 at 9-12; Ex. 4 at 48:5-49:16, 89:9-90:24, 118:5-119:6, 129:17-131:5, 151:9-152:7; Ex. 5 at 45:17-47:22. Liquidia requested the inventor depositions in August and Dr. Waxman’s deposition on October 1, but UTC scheduled all depositions relevant to improper inventorship to occur after Oct. 30.<sup>3</sup>

2. **Anticipation by 2020 Press Release** (Ex. A, § II.B.1). Liquidia disclosed this contention on Oct. 30: “Because the ’327 patent is not entitled to an April 17, 2020 priority date, additional prior art renders the Asserted Claims invalid for anticipation [], including [2020 Press Release].” Ex. 2 at 7; *see also id.* at 1-2. The Oct. 30 contentions put UTC on notice that the 2020 Press Release “provides data establishing inhaled treprostинil improves exercise capacity, 6MWD, reduced NT-proBNP, and reduced time to first clinical worsening event.” *Id.* at 7.

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<sup>3</sup> It is the substance of the named inventors’ testimony—not their “dates of employment” (D.I. 241 at 2)—that is relevant and the basis for Liquidia’s supplementation. *See* Ex. 3 at 9-12 (summarizing deposition testimony of Dr. Smith, Dr. Peterson, and Dr. Laliberte).

UTC supplemented its interrogatory response regarding priority on Nov. 19, and the 2020 Press Release is prior art based on UTC's lack of priority. *See* Ex. 11. The Dec. 3 contentions addressed UTC's supplemental interrogatory response and provided further detail, citing testimony from Drs. Smith, Peterson, and Deng obtained *after* Oct. 30. Ex. 3 at 7-9, n.3.<sup>4</sup>

3. **Anticipation by Prior Public Use** (Ex. A, § III). As the Court stated during the Dec. 5 teleconference, “th[e] issue of prior public use of Tyvaso has been a critical issue running through the course of the litigation” and is “certainly a topic that doesn’t take anyone by surprise.” Ex. 6 at 39:1-10. Liquidia put UTC on notice of this contention in its June 3, 2024 contentions, by detailing various examples of prior use and including relevant testimony from Dr. Nathan. Ex. 7 at § III.A.3; *see also* Ex. 2 at § III.A.3. Prior public use was also disclosed as early as April 1, 2024 in Liquidia’s Preliminary Injunction Opposition Brief and Dr. Channick’s supporting declaration. D.I. 52 at 1-2, 11; D.I. 54 at § V.C.2. The Dec. 3 contentions provided further detail on this legal theory, citing deposition testimony obtained *after* Oct. 30. Ex. 3 at 12-19.
4. **Anticipation by Faria-Urbina 2018** (Ex. A, § VI.E). Liquidia disclosed its intent to rely on Faria-Urbina 2018 for its prior art invalidity theories in its June 3 and Oct. 30 contentions, and as early as April 1, 2024 in its PI briefing relating to prior public use, which is another form of anticipation. Ex. 7 at §§ III.B.6, V.C; Ex. 2 at §§ III.B.6, V.C; D.I. 54 at ¶¶ 48, 53.
5. **Obviousness by Faria-Urbina 2018** (Ex. A, § VII.D). Liquidia disclosed its obviousness based on Faria-Urbina 2018 in its Oct. 30 contentions. Ex. 2 at § V.C.
6. **Obviousness by 2017 INCREASE Study Description in combination with Faria-Urbina 2017 or Agarwal 2015 and Saggar 2014** (Ex. A, § VII.G). The prior art combination of the 2017 INCREASE Study Description, Agarwal 2015, and Saggar 2014 was previously disclosed in Liquidia’s June 3 contentions. Ex. 7 at § V.F.<sup>5</sup> UTC was well-aware of Liquidia’s reliance on Faria-Urbina 2018 as prior art as early as April 2024, and including Oct. 30, and thus the combination of the 2017 INREASE Study Description with Faria-Urbina 2018 and Saggar 2014 is not a new legal theory.
7. **Inequitable Conduct by Peter Smith** (Ex. A, § IX.I-M). Liquidia agrees to withdraw its inequitable conduct allegations concerning Dr. Smith.

UTC’s letter fails to articulate any surprise, let alone prejudice it has suffered and instead speaks in hypotheticals, vaguely stating that it “could have asked different or additional questions at depositions” and “pursued different or additional discovery strategies[,]” without providing specific examples. D.I. 241 at pp. 2-3. As explained above, by Oct. 30 or earlier, UTC was on notice of each identified legal theory and prior art reference, and was free to explore those issues on re-direct examination with the witnesses, which all occurred after Oct. 30 and because UTC represented—all inventors, Dr. Faria-Urbina (co-author of Faria-Urbina 2018), Dr. Tapson (INCREASE study steering committee member), and Dr. Waxman (co-author of Faria-Urbina 2018, Agarwal 2015, and INCREASE study steering committee head). For example, on re-direct,

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<sup>4</sup> UTC never informed Liquidia that it intended to move to strike anticipation by the 2020 Press Release, and UTC did not meet and confer on this issue. *See* Ex. G (no reference to 2020 Press Release). For this reason, the Court should deny UTC’s motion to strike Liquidia’s contentions regarding anticipation by the 2020 Press Release.

<sup>5</sup> Liquidia’s Dec. 3 contentions therefore do not “mix and match” prior art combinations as done in *Chevron*. *See* D.I. 241 at 3.

UTC asked inventor Smith follow-up questions relevant to conception and inventorship; thus, Liquidia's allegedly late disclosures in no way prevented UTC from exploring the known legal theory of improper inventorship. *See* Ex. 4 at 233:17-240:12. Dr. Waxman was deposed on Dec. 12, over a week after Liquidia's Dec. 3 contentions, but UTC counsel chose to limit his re-direct examination to a brief line of questions. *See* Ex. 5 at 222:10-229:20; *see also id.* at 229:22-231:12.

Further, at no time during the meet-and-confer process, or after, did UTC make any attempt to establish surprise or prejudice. During the Dec. 6 meet-and-confer, Liquidia noted that trial was six months away, UTC's responsive expert report was due in January, and specifically asked UTC what prejudice it has suffered. UTC provided no response, as memorialized in an email from Karen Keller to Michael Flynn. *See* Ex. 8. And despite multiple emails after the conference, UTC did not assert surprise, prejudice, or why trial would be disrupted, and rejected Liquidia's offer to cure any non-alleged prejudice by granting UTC additional time to serve its responsive expert report. *See* Ex. 9 at 1-2.

UTC also cannot complain of any prejudice arising from Liquidia's interrogatory responses—which Liquidia supplemented in accordance with its ongoing duty under Rule 26—because UTC failed to conduct a meaningful meet-and-confer. Ex. G at 3 (“Liquidia believes UTC is no longer seeking to exclude these interrogatory supplementations.”). UTC's letter provides no analysis as to why the Court should strike the Nov. 22 and Dec. 2 supplemental interrogatory responses. Finally, to the extent any prejudice exists, it could have been readily cured by Liquidia's proposal to provide UTC with additional time to prepare its responsive expert reports, which UTC rejected on Dec. 17 without explanation. (Ex. 9 at 1-2.)

#### **C. Factor No. 3 (likelihood of disruption of the trial)**

Trial will not be disrupted.

#### **D. Factor Nos. 5 (explanation for failure to disclose) and 6 (bad faith)**

Liquidia disclosed its legal theories and diligently supplemented to account for significant discovery that took place after Oct. 30. It is thus plainly false that Liquidia “already possessed the evidence on which it now relies” for improper inventorship. D.I. 241 at 3.<sup>6</sup> Regarding the allegedly “new” anticipation and obviousness contentions, Liquidia did not fail to disclose any prior art or theory of invalidity, as Liquidia put UTC on notice of its prior public use defense and the Faria-Urbina 2018 reference as early as April 2024. And UTC makes no allegations Liquidia acted in bad faith.

The *Pennypack* factors all strongly favor denying UTC's motion. Moreover, UTC essentially seeks to prevent Liquidia from relying on the significant discovery that occurred after Oct. 30 that support Liquidia's contentions—discovery UTC scheduled to occur after Oct 30. For the reasons presented herein, UTC's motion to strike should be denied.

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<sup>6</sup> The *TQ Delta* case cited by UTC is distinguishable because, there, the contentions disclosed a brand-new doctrine of equivalents theory that required additional third party discovery; here, UTC has not specified any additional fact discovery required to address Liquidia's Dec. 3 contentions. *See* Ex. I.

Respectfully submitted,

*/s/ Nathan R. Hoeschen*

Nathan R. Hoeschen (No. 6232)

cc: Clerk of the Court (by CM/ECF)  
All counsel of record (by CM/ECF and email)

# EXHIBIT 1

## Strosnick, Lauren

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**From:** Ediger, Benjamin <bediger@mwe.com>  
**Sent:** Saturday, November 2, 2024 5:18 PM  
**To:** Preston, Rachel L; Minn, Robert; jblumenfeld@morrisnichols.com; mflynn@morrisnichols.com; Carsten, Douglas; Dykhuis, Art; Burrowbridge, Adam; WJackson@goodwinlaw.com; Cheng, Katherine; Romeo, Eric; Lobel, Louis  
**Cc:** z/Liquidia v UTC 308970-201; UTCvLiquidia-Del-23cv975; DG-ILD; Karen Keller; nhoeschen@shawkeller.com; Emily DiBenedetto  
**Subject:** UTC v. Liquidia (23-975) - Further to subject matter addressed at parties' October 23, 2024 meet and confer

### [External]

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Counsel,

Thank you for the meet and confer on October 23, 2024. Please see UTC's position on subject matter addressed during the meet and confer and our understanding of positions Liquidia took.

#### Final Contentions:

Liquidia proposed extending the current, Court-ordered October 30, 2024 deadline for final contentions (D.I. 45 at 3(g)(iii)(2)) through at least the close of fact discovery. UTC adhered to the Court-ordered deadline, which is binding on the parties unless and until the Court orders otherwise. UTC does not agree to an extension.

#### UTC's Interrogatories Nos. 2-9:

Interrogatories Nos. 2, 3, 5, and 6: Liquidia agreed to supplement their responses to these Interrogatories.

- Interrogatory No. 2: This Interrogatory calls for a detailed description of Liquidia's R&D regarding the administration of Yutrepia to patients having PH-ILD. Liquidia agreed to supplement by providing a narrative response. Please provide your update within a week so that we can assess it and raise any remaining disputes with the Court.
- Interrogatory No. 3: This Interrogatory calls for a detailed description of whether Liquidia contends that Yutrepia is safe and effective for PH-ILD patients, and if so, why. Liquidia also agreed to supplement by providing a narrative response. Accordingly, UTC understands that Liquidia will update its current response to indicate whether it contends Yutrepia is safe and effective for PH-ILD patients. UTC also understands that Liquidia will update its current response to comply with FRCP 33(d) and ensure that any citations in Liquidia's supplement comply with FRCP 33(d). Please provide your update within a week so that we can assess it and raise any remaining disputes with the Court.
- Interrogatories Nos. 5 and 6: Liquidia's counsel agreed to supplement these Interrogatories if appropriate. Interrogatory No. 5 calls for a detailed description of "how Yutrepia™ compares to or differs from Tyvaso® and Tyvaso DPI®." UTC expects that Liquidia will supplement their response to Interrogatory No. 5 with respect to the following categories, along with an identification of all supporting documents and things: "(a) patient population; (b) target market; (c) active ingredient; (d) delivery device; (e) dosage or strength; (f) effectiveness or efficacy; (g) quality or safety; and (h) clinical research phase or approval status[.]" Please provide your update within a week so that we can assess it and raise any remaining disputes with the Court.

Interrogatories Nos. 4, 7, and 9: These Interrogatories are relevant for multiple reasons, including damages, indirect infringement, and secondary indicia of nonobviousness, including commercial success, as noted in our emails of October 3, 8, and 14, 2024. Liquidia has produced documents identifying the existence of this information, establishing that Liquidia is withholding responsive documents and things from UTC. See, e.g., LIQ\_PH-ILD\_00130620 at -628 [REDACTED]

[REDACTED]. Liquidia informed UTC that it will not supplement its responses to any of these Interrogatories, and that Liquidia will not identify any individuals that are most knowledgeable about these Interrogatories, their job titles, and the subject matter on which they are knowledgeable. Liquidia asserts that the subject matter sought in these Interrogatories is not relevant until Yutrepia launches. It appears that the parties are at an impasse, and thus UTC reserves the right to raise these issues with the Court.

Interrogatory No. 8: Liquidia reiterated that Section VII of its First Amended Invalidity Contentions is fully responsive to this Interrogatory, specifying that any supplement to their response for this Interrogatory would be a verbatim copy of Section VII of its First Amended Invalidity Contentions. We note that this Interrogatory requested additional information, but we understand that Liquidia is incapable and/or refuses to provide a further response.

**Liquidia's production of documents that cannot be rendered, including Volume 9:**

Liquidia's response to UTC Interrogatory No. 2 cites "Liquidia's document production LIQ\_PH-ILD\_009." Many of the documents contained within LIQ\_PH-ILD\_009 have been replaced with slipsheets stating that the "Document Cannot be Rendered." Looking in Volume 9 and in the rest of Liquidia's production, there are over 198 documents that similarly contain slipsheets stating "Document Cannot be Rendered," 55 of which contain no file path metadata. Please look into why these documents could not be produced and update us not later than Monday, November 4, 2024.

**UTC's Requests for Production:**

RFP No. 24: Liquidia represented that to the extent it possessed responsive and relevant documents, they were produced. However, Liquidia failed to produce any communications with Drs. Nicholas S. Hill, Jeremy P. Feldman, Sandeep Sahay, Raymond L. Benza, Ioana R. Preston, David Badesch, Robert P. Frantz, Savan Patel, Ashley Galloway, or Todd M. Bull concerning the applicability of the INSPIRE study data and results to PH-ILD patients or the improvement of exercise capacity. Please confirm that Liquidia will produce communications concerning the INSPIRE study data and results, including communications concerning the applicability of the study data and results to PH-ILD patients and the improvement of exercise capacity in all patients.

RFP No. 25: Please confirm whether Liquidia would agree to produce 4 sample Yutrepia kits as requested.

RFP No. 49: Liquidia agreed to produce documents sufficient to identify Liquidia's organization structure and departmental management structure. Please produce those documents promptly.

RFP No. 73: Liquidia stated that it would not produce settlement or license agreements because none exist.

RFPs Nos. 79 – 80: Liquidia stated that it would respond and produce documents, to the extent they exist, but only if UTC expressly authorized Liquidia's counsel to discuss the documents and things sought by such requests with Roger Jeffs. UTC declines to provide this authorization and requests that Liquidia

investigate if Liquidia already (improperly) has information from Roger Jeffs on this subject matter. If so, UTC demands Liquidia provide any communications, documents or things that have already been shared.

RFPs Nos. 5, 11 – 15, 37, 51 – 53, 57, 60 – 61, 68, 74, and 81: Liquidia informed UTC that it will not produce documents and things in response to these RFPs or at least will not produce such documents and things until Yutrepia launches. Liquidia asserted that these RFPs were only relevant to damages, and Liquidia maintained that their objection was proper under the Hatch-Waxman Act because Yutrepia has not been approved or commercialized. This was Liquidia’s position for RFPs Nos. 11 – 15; UTC’s counsel understands that the parties are also at an impasse on these additional RFPs and will proceed accordingly.

- RFPs Nos. 51 and 52: Liquidia’s counsel represented that [REDACTED]

[REDACTED] Indeed, Liquidia’s CFO and COO Michael Kasetta is quoted in Liquidia’s September 11, 2024 press release entitled “Liquidia Corporation Announces Raise of \$67.5 Million from New Common Stock Financings and \$32.5 Million Advance from HealthCare Royalty Under Current Financing Agreement,” stating that “[w]e believe we are financially well-positioned to continue ongoing commercial development of YUTREPIA . . . .” LIQUIDIA, <https://www.liquidia.com/news-releases/news-release-details/liquidia-corporation-announces-raise-675-million-new-common> (last visited Nov. 2, 2024). These pre-market materials are at least relevant to both direct infringement and inducement, and thus UTC demands that Liquidia produce these documents and things.

RFPs Nos. 7, 26, 45, 50, 54 – 56, 59, 69, and 82 – 84: Liquidia stated that it sufficiently responded to these requests. However, UTC maintains its position that Liquidia’s production in response to these RFPs is deficient.

- RFP No. 26: Liquidia’s counsel represented that it has produced all responsive documents. Yet we have identified the existence of responsive documents that Liquidia still has not produced. Some examples are documents corresponding to the entries in the NDA 213005 chronology log produced at LIQ\_PH-ILD\_00130689 and the IND 129819 chronology log produced at LIQ\_PH-ILD\_00130690. For example, it appears that the SN0062 submission from NDA 213005 has been withheld. UTC’s counsel requests that Liquidia identify where this submission has been produced or that Liquidia update their production.
- RFP No. 69: Liquidia represented that it produced all Board meeting presentations; UTC’s assessment of whether any Board meeting presentations have been omitted is ongoing and we reserve the right to request that Liquidia produce any withheld presentations.
- “Product Comparisons” RFPs identified in UTC’s October 14, 2024 letter: Liquidia represented that it produced all documents and things responsive to these requests; accordingly, we understand that Liquidia believes its production is both an exhaustive reflection of the differences reflected in these documents and things and exhaustive with respect to the information available to Liquidia.
- “Yutrepia Clinical Trials” RFPs identified in UTC’s October 14, 2024 letter: Liquidia represented that it produced ASCENT study and trial information and data. UTC therefore understands that Liquidia is representing that as of October 23, 2024 the ASCENT study and trial had not generated any data other than what Liquidia had produced as of October 23, 2024. UTC expects Liquidia to continue to promptly produce all data generated by the ASCENT study and trial on an ongoing basis.

Thank you,

Benjamin Ediger, PhD (HE/HIM/HIS)

Associate

**McDermott Will & Emery LLP** 300 Colorado Street, Suite 2200, Austin, TX 78701

\*\*\*\*\*  
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# EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS  
CORPORATION,

Plaintiff,

v.

LIQUIDIA TECHNOLOGIES, INC.,

Defendant.

C.A. No. 1:23-cv-00975-RGA

**DEFENDANT LIQUIDIA TECHNOLOGIES, INC.’S  
SECOND AMENDED INVALIDITY CONTENTIONS**

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Defendant Liquidia Technologies, Inc. (“Liquidia”) hereby submits its Second Amended Invalidity Contentions with respect to all claims of U.S. Patent No. 11,826,327 (the “’327 patent” or “Asserted Patent” or “Patent-in-Suit”) asserted by United Therapeutics Corp. (“UTC” or “Plaintiff”) in UTC’s Initial Infringement Contentions dated May 2, 2024. Specifically, UTC asserts infringement of claims 1-11 and 14-19 of the ’327 patent (“the Asserted Claims”).

Liquidia notes that fact discovery is still ongoing, with more than ten remaining depositions, at least five of which are scheduled after the close of fact discovery. Despite several meet and confers, including as recent as October 23, 2024, there are numerous issues pending before the Court and Liquidia anticipates additional discovery disputes requiring the Court’s intervention. On October 23, the parties expressly discussed serving final contentions at the end of fact discovery. UTC indicated it would respond to Liquidia’s proposal to serve final contentions at the completion of fact discovery, including depositions occurring beyond the close of fact discovery. UTC failed to respond and instead served its final infringement contentions. As such, Liquidia reserves the right to supplement its invalidity contentions based on upcoming depositions, as well as documents that have been produced and have not yet been produced that may support its contentions, including but not limited to its contentions regarding obviousness, § 112 enablement, and inequitable conduct. Moreover, UTC produced over 200,000 pages of documents after August 12, 2024, the deadline for the substantial completion of document production and has not indicated its production is complete. UTC has also not substantiated its response to Liquidia’s Interrogatory No. 2 regarding UTC’s objective indicia of non-obviousness, including motivation and expectation of success. Thus, Liquidia reserves the right to supplement its position regarding the same. Further, UTC has not substantiated its response to Liquidia’s Interrogatory No. 5 regarding UTC’s basis supporting that the claims of the ’327 patent have a priority date of April 17, 2020. In view of ongoing discovery and disputes, Liquidia anticipates supplementing its

identification of prior art, to include at least UTC's February 24, 2020 press release titled "United Therapeutics Announces Increase Study of Tyvaso Meets Primary and all Secondary Endpoints." Liquidia incorporates the testimony and exhibits from the depositions of Noah Byrd, Rajan Saggar, Rajeev Saggar, Dean Bunce, Marina Faria-Urbina, and Kishan Parikh. In view of the continuing discovery and disputes, Liquidia anticipates further supplementation of its invalidity and unenforceability positions including at least the following:

- supplementation of Liquidia's defenses, including improper inventorship of the '327 patent; and
- supplementation of Liquidia's inequitable conduct allegations following upcoming depositions, including the depositions of Shaun Snader, Stephen Maebius, Martine Rothblatt, and the named inventors of the '327 patent.

Liquidia will further supplement and serve final invalidity contentions at the close of fact discovery, including fact depositions in this case.

## I. GENERAL INFORMATION

These contentions are based on information reasonably available to Liquidia at this time, and may require subsequent amendment, alteration, or supplementation. Consequently, Liquidia reserves the right to amend, alter, or supplement these contentions based on further prior art, investigation, fact or expert discovery, evaluation of the scope and content of the prior art, any claim construction from the Court, or as a result of UTC's Asserted Claims and contentions. Moreover, these contentions may be in the alternative and do not substitute any concession by Liquidia for the purposes of claim construction or infringement. *See Fed. R. Civ. P. 8(d).*

In these First Amended Invalidity Contentions, Liquidia has identified specific combinations of primary and secondary prior art references upon which it intends to rely. However, there is a large volume of background art relevant to invalidity, on which Liquidia relies

protocol or results, which UTC’s expert, Dr. Nathan, testified would be required. (D.I. 28 (“Nathan Decl.”), ¶¶207-208; 3/10/2024 Deposition Transcript of Dr. Steven D. Nathan (“Nathan Dep. Tr.”) at 163:16-165:6.)

Moreover, independent of UTC’s arguments, Asserted Claims 1-11 and 14-19 are not entitled to claim priority to the ’810 Provisional. Claim 1 recites a “method of improving exercise capacity in a patient having pulmonary hypertension associated with interstitial lung disease.” To the extent “improving exercise capacity” is a limitation, the ’810 Provisional does not provide any written description or enablement support for improving exercise capacity. Further, the ’810 Provisional does not provide any data with respect to the six-minute walk distance test, nor describes a pulsed inhalation device as currently claimed. Therefore, the Asserted Claims of the ’327 patent are not entitled to the April 17, 2020 priority date of the ’810 Provisional.<sup>1</sup> Because the ’327 patent is not entitled to an April 17, 2020 priority date, additional prior art renders the Asserted Claims invalid for anticipation and obviousness, including UTC’s February 24, 2020 press release title “United Therapeutics Announces INCREASE Study of Tyvaso® Meets Primary and All Secondary Endpoints.” See <https://www.prnewswire.com/news-releases/united-therapeutics-announces-increase-study-of-tyvaso-meets-primary-and-all-secondary-endpoints-301009562.html>. This press release provides data establishing inhaled treprostinil improves exercise capacity, 6MWD, reduced NT-proBNP, and reduced time to first clinical worsening event. *Id.*

### III. SCOPE AND CONTENT OF THE PRIOR ART FOR THE ’327 PATENT

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<sup>1</sup> Should UTC change its position and claim a priority date for the ’327 patent post-dating the currently alleged April 17, 2020 priority date, Liquidia reserves the right to amend its invalidity contentions to add additional prior art references that post-date the April 17, 2020 priority date. Liquidia’s reservation of rights does not constitute an admission that the ’327 patent is entitled to the April 17, 2020 priority date.

correlated with improvements in exercise capacity as measured by the 6MWD.<sup>2</sup>

### **3. Long Before April 2020, Physicians Were Using Inhaled Treprostinil to Treat PH-ILD**

While Tyvaso® was approved for PH-ILD in 2021, the idea and demonstrated success of using treprostinil, including inhaled treprostinil, in Group 3 patients, including PH-ILD patients, predates both Tyvaso®’s approval date for PH-ILD as well as the April 17, 2020 filing date of the ’327 patent. Indeed, the idea of treating Group 3 PH, including PH-ILD, by using inhaled prostacyclin, was shown to be safe as early as 1999. (H. Olschewski, et al., Inhaled Prostacyclin and Iloprost in Severe Pulmonary Hypertension Secondary to Lung Fibrosis, *Am. J. Respir. Crit. Care. Med.* 160:600-607 (1999) (LIQ\_PH-ILD\_00002398) (“Olschewski 1999”).)

Multiple studies reported positive uses of treprostinil in WHO Group 3 patients, including those with PH-ILD. For example, in 2009 in a study supported by a UTC research grant, Saggar, et al. reported that a patient who was administered parenteral treprostinil showed improvement in the 6MWD, WHO functional class, BNP level, quality of life survey score, Borg Dyspnea Scale, and spirometric function, including an improvement in FVC (% predicted). (R. Saggar, et al., Treprostinil to Reverse Pulmonary Hypertension Associated with Idiopathic Pulmonary Fibrosis as a Bridge to Single-Lung Transplantation, *J. Heart and Lung Transplant.* 28:964-7 (2009) (LIQ\_PH-ILD\_00002986) (“Saggar 2009”) at LIQ\_PH-ILD\_00002987.)

In 2014, in another study funded partly by UTC, Saggar et al. examined, amongst other

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<sup>2</sup> Deposition Transcript of Aaron Waxman, M.D., Ph.D. in *United Therapeutics Corp. v. Liquidia Techs., Inc.*, IPR2021-00406 (P.T.A.B. Jan. 8, 2022) (LIQ\_PH-ILD\_00000579) (“Waxman IPR Dep. Tr.”) at 40:12-14, 42:14-22, 152:1-8; Deposition Transcript of Andrew Clark, Ph.D. in *United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 20-755-RGA (D. Del. Jan. 14, 2022) (LIQ\_PH-ILD\_00000879) (“Clark Dep. Tr.”) at 55:19-56:3; Testimony of Aaron Waxman, M.D. Ph.D., Trial Transcript Vol. III in *United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 20-755-RGA (D. Del. Mar. 30, 2022) (“Waxman Trial Tr.”) (LIQ\_PH-ILD\_00000792) at 651:14-22; *id.* at 652:11-653:2.

things, hemodynamics, 6MWD, and quality of life indices in patients with pulmonary fibrosis (a form of PH-ILD) who were administered parenteral treprostinil. (*See* Saggard 2014 at LIQ\_PH-ILD\_00000226.) The authors reported “significant improvements in right heart h[e]modynamics,” “improvements [] in 6MWD,” improvements in quality of life indices as measured in the 36-Item Short Form Health Survey Mental Component Summary aggregate and the University of California San Diego Shortness of Breath Questionnaires, and improvements in BNP levels. (Saggard 2014 at LIQ\_PH-ILD\_00000226, LIQ\_PH-ILD\_00000228 (Tbl. 2), LIQ\_PH-ILD\_00000229, LIQ\_PH-ILD\_00000231.) The study also indicated an improvement in FVC, % predicted following treprostinil treatment. (*Id.* at LIQ\_PH-ILD\_00000228 (Tbl. 2).)

Similarly, a 2012 patent publication from UTC claimed, “[a] method of treating a condition associated with an interstitial lung disease, comprising parenteral administration to subject in need thereof an effective amount of [t]reprostinil. . . wherein said condition is pulmonary hypertension, which [is] a complication of said interstitial lung disease.” (US 2013/0096200 (UTC\_PH-ILD\_010774) (“Wade 200”) at cl. 1.) The patent disclosed studies showing a positive effect of intravenous treprostinil in patients with IPF and PH. (*Id.* at [0082].)

Several studies further demonstrated that inhaled treprostinil was effective (including in improving exercise capacity) in Group 3 PH, including PH-ILD. In 2011, Schirro and Waxman described that inhaled treprostinil, delivered according to the “usual protocol starting with three breaths four times a day,” in patients with PH and parenchymal lung disease (a form of Group 3 PH) showed improvements in the 6MWD and on the Borg Dyspnea Scale. (A. Schirro and A. Waxman, Inhaled treprostinil therapy in patients with pulmonary hypertension and parenchymal lung disease, *Eur. Respir. J.* 38:p2385 (2011) (LIQ\_PH-ILD\_00002474) (“Schirro and Waxman 2011”) at Abstract; *see also* *Eur. Respir. J.* Vol. 38 Suppl. 55 Table of Contents (LIQ\_PH-ILD\_00002462).) The authors concluded that inhaled treprostinil “may offer an effective and well

tolerated treatment in subjects with PLD and shortness of breath exacerbated by PH.” (*Id.*)

In 2015, Agarwal and Waxman examined inhaled treprostinil in WHO Group-3 PH patients, including patients with restrictive disease, and saw significant improvements in the 6MWD. (M. Agarwal and A.B. Waxman, Inhaled Treprostinil in Group-3 Pulmonary Hypertension, *J. Heart and Lung Transplant.* 34(4):S343 (2015) (UTC\_PH-ILD\_009828 (“Agarwal 2015”)).) The authors concluded that “Group-3 PH can be effectively and safely treated” with inhaled treprostinil and that “[i]nhaled [t]reprostinil may offer a well-tolerated treatment in advanced lung disease patients complicated by pulmonary vascular remodeling.” (Agarwal 2015 at UTC\_PH-ILD\_009828 (Conclusion).)

In 2016, researchers in a UTC funded study reviewed 6MWD data from WHO Group 1–5 patients treated with inhaled treprostinil and reported an improvement in the 6MWD in the retrospective study, including in patients with PH-ILD. (K. Parikh, et al., Safety and Tolerability of High-dose Inhaled Treprostinil in Pulmonary Hypertension, *J. Cardiovasc. Pharmacol.* 67(4): 322-25 (2016) (UTC\_PH-ILD\_010599) (“Parikh 2016); see also (LIQ\_PH-ILD\_00002439).)

Then again, in 2018, Faria-Urbina and colleagues looked at 22 patients with PH-associated with lung disease who were treated with inhaled treprostinil. (M. Faria-Urbina, et al., Inhaled Treprostinil in Pulmonary Hypertension Associated with Lung Disease, *Lung* 196:139-46 (2018) (UTC\_PH-ILD\_009936) (“Faria-Urbina 2018”)). Their assessment concluded that Group 3-PH patients treated with inhaled treprostinil saw significant improvements in the 6MWD.

On the basis of the positive studies described above and the rationale for using inhaled treprostinil in PH-ILD patients, physicians, regularly prescribed inhaled treprostinil to PH-ILD

patients off-label.<sup>3</sup> They did so before the April 2020 filing date of the '327 patent, before the results of the INCREASE trial were published, and before Tyvaso® was approved for the treatment of PH-ILD. Physicians started prescribing Tyvaso® to PH-ILD patients almost immediately after it was approved in 2009, and did so according to the dosing regimen described in the Tyvaso® label. (D.I. 54 (“Channick Decl.”), ¶52.) Even UTC’s expert, Dr. Steven Nathan, acknowledged that he likely used inhaled treprostinil off-label to treat PH-ILD patients, and certainly used another therapy, sildenafil, to treat PH-ILD off-label. (Nathan Dep. Tr. at 88:19-89:21, 92:15-20, 96:6-8.)

#### **4. The INCREASE Study Confirmed Known Benefits of Inhaled Treprostinil in PH-ILD Patients**

The studies described above also formed the rationale and motivation for the design and conduct of the INCREASE study, which was a large clinical study for inhaled treprostinil in PH-ILD patients that began in 2015. (Waxman 2021 at UTC\_PH-ILD\_010790-829.) In particular, the New England Journal of Medicine publication for the INCREASE study cited to several of the studies noting

Data from previously completed pilot studies suggest that inhaled treprostinil can improve hemodynamics and functional capacity in patients with group 3 pulmonary hypertension. Therefore, the objective of the INCREASE trial was to evaluate the safety and efficacy of inhaled treprostinil in patients with [PH-ILD].

(*Id.* at UTC\_PH-ILD\_010791, UTC\_PH-ILD\_010799 (citing Agarwal 2015, Faria-Urbina 2018,

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<sup>3</sup> A 2015 survey of 30 U.S. pulmonary vascular disease centers used PAH therapy in patients with non-group 1 PH, including treprostinil. (A. W. Trammell, et al., Use of pulmonary arterial hypertension-approved therapy in the treatment of non-group 1 pulmonary hypertension at US referral centers, *Pulm. Circ.* 5(2):356-63 (2015) (LIQ\_PH-ILD\_00002539) (“Trammel 2015”).) In 2017, the Giessen PH registry showed that 78% of WHO Group 3 patients, including PH-ILD patients, were on PAH therapies. (H. Gall, et al., The Giessen Pulmonary Hypertension Registry: Survival in pulmonary hypertension subgroups, *J. Heart Lung Transplant.* 36(9):957-67 (2017) (LIQ\_PH-ILD\_00001617) (“Gall 2017”) at 965.)

results, Agarwal concludes that “Group-3 PH can be effectively and safely treated” with inhaled treprostinil and that “[i]nhaled [t]reprostinil may offer a well-tolerated treatment in advanced lung disease patients complicated by pulmonary vascular remodeling.” (*Id.* (Conclusion).) Agarwal 2015 further states that “[a] prospective clinical trial is indicated.” (*Id.*)

#### **5. Saggar 2014**

Saggar 2014 is an article partly funded by UTC and authored by Rajeev Saggar and others titled “Changes in right heart haemodynamics and echocardiographic function in an advanced phenotype of pulmonary hypertension and right heart dysfunction associated with pulmonary fibrosis,” published on pages 123–129 of volume 69 of *Thorax* in 2014. (Saggar 2014 at LIQ\_PH-ILD\_00000226.)

In Saggar 2014, the authors report on the administration of parenteral treprostinil in 15 patients with pulmonary fibrosis, which is a form of PH-ILD. (Saggar 2014 at LIQ\_PH-ILD\_00000226 (Abstract).) Patients showed “significant improvements in right heart haemodynamics” (*id.*) as well as “6MWD improvements following 12 weeks of parenteral treprostinil therapy (mean 59 m; p<0.001).” (*Id.* at LIQ\_PH-ILD\_00000229.) Patients also saw their BNP (brain natriuretic peptide) levels fall from 558 pg/ml to 228 pg/ml after 12 weeks. (*Id.* at LIQ\_PH-ILD\_00000230 (Tbl. 4).) Further, the authors reported a change in FVC % predicted from 62 % at baseline to 63% after 12 weeks. (*Id.* at LIQ\_PH-ILD\_00000228 (Tbl. 2).)

#### **6. Faria-Urbina 2018**

Faria-Urbina 2018 is a publication titled “Inhaled Treprostinil in Pulmonary Hypertension Associated with Lung Disease” by Mariana Faria-Urbina, Rudolf K.F. Oliveira, Manyoo Agarwal, and Aaron B. Waxman. It was published in 2018 on pages 139-146 in volume 196 of the journal *Lung*. (M. Faria-Urbina, et al., Inhaled Treprostinil in Pulmonary Hypertension Associated with Lung Disease, *Lung* 196:139-146 (2018) (“Faria-Urbina 2018”) (UTC\_PH-ILD\_009936).)

Faria-Urbina 2018 describes a retrospective study in patients with Group 3 PH who were treated with inhaled treprostinil at three breaths (18 µg) four times daily (72 µg) with “doses [] increased as tolerated by three additional breaths (18 µg) per dosing session every 3–7 days to achieve a dose of at least 9–12 breaths or more ( $\geq 54$  µg) four times daily . . . .” (*Id.* at UTC\_PH-ILD\_009937 (Treatment regimen and follow-up).) Nine patients were classified as having ILD, and across all patients the mPAP, PAWP, and PVR were  $44\pm 10$  mmHg,  $10\pm 4$  mmHg, and  $8.1\pm 3.6$  WU respectively. (*Id.* at UTC\_PH-ILD\_009938 (Baseline Characteristics).) Patients were followed for at least three months while on treprostinil. (*Id.* at UTC\_PH-ILD\_009937 (Introduction).)

The authors of Faria-Urbina 2018 report 21 out of the 22 patients in the study “improved (or maintained) functional class[,]” “19 improved SpO<sub>2</sub>; 10 had follow-up with 6MWT—all of them showing improvement in the distance walked.” (*Id.* at UTC\_PH-ILD\_009939.) On the basis of the data, the study concludes that “patients with Group 3 PH treated with [inhaled treprostinil], therapy with [inhaled treprostinil] significantly improved WHO-FC and 6MWT distance” (*id.* (Discussion)) and the results suggest that “iTRE is safe in patients with Group 3 PH and evidence of pulmonary vascular remodeling in terms of functional class, gas exchange, and exercise capacity” (*id.* at UTC\_PH-ILD\_009936 (Abstract)). The authors concluded that inhaled treprostinil was safe in Group 3 PH patients and showed evidence of improving exercise capacity in those patients. (*Id.* (Abstract, Conclusions).)

In 2018, Dr. Waxman, one of the authors on Faria-Urbina 2018, gave a presentation at UTC’s Science Day on the findings of Faria-Urbina. (A. Waxman, *The iTRE Study: Therapeutic Opportunity for Inhaled Treprostinil in Patients with PH Secondary to Primary Pulmonary Vascular Disease*, UTHR Science Day 2018 (2018) (“Waxman Presentation 2018”) at Slides 11-16 (LIQ\_PH-ILD\_00101301).) In that presentation, which bears UTC’s logo, he noted that 41%

of Group 3 PH patients in the study had “ILD,” meaning they had PH-ILD. (*Id.* at Slide 13.) He further reported that patients in the study showed an improvement in 6MWD of +65 m (p = 0.022), meaning the change in the 6-min walk distance was significant. (*Id.* at Slide 13.)

### 7. Parikh 2016

Parikh 2016 is an article titled “Safety and Tolerability of High-dose Inhaled Treprostinil in Pulmonary Hypertension” by Kishan S. Parikh and others that was published on pages 322-325 of Volume 67 Issue 4 of the *Journal of Cardiovascular Pharmacology* in 2016. (K. Parikh., et al., Safety and Tolerability of High-dose Inhaled Treprostinil in Pulmonary Hypertension, *J. Cardiovasc. Pharmacol.* 67(4); 322–25 (2016) (“Parikh 2016”) (UTC\_PH-ILD\_010599).)

Parikh 2016 discloses a retroactive study of 80 PH patients at the Duke University Medical Center PH Clinic. Out of the 80 patients, 25 patients were categorized as having Group 3 PH, 6 of which had pulmonary hypertension associated with interstitial lung disease. (*Id.* at UTC\_PH-ILD\_010607.) The PH clinic protocol put patients on a single administration dosing regimen of 3 breaths (18 mcg)/initial session, 6 breaths (36 mcg)/second session, and then doses were titrated as tolerated, based on side effects, by 1 breath daily until a maximum dosage of 12 breaths (72 mcg) four times daily was achieved. (*Id.* at UTC\_PH-ILD\_010600 (Methods, Study Population).) At least 6 mcg of treprostinil was administered per breath. Because the study was conducted to assess the tolerability of high dose inhaled treprostinil, it only followed patients at the clinic who were prescribed doses of inhaled treprostinil that were greater than 9 breaths four times daily. (*Id.*)

Baseline data was collected from all 80 patients, and then data for 49 patients was collected at Follow-up Visit 1 and data for 39 patients was collected at Follow-up Visit 2. (*Id.* at UTC\_PH-ILD\_010601 (Results).) The study found that the average change in the 6-minute walk distance was 3.9 meters from Baseline to Follow-up Visit 1, and 31.6 meters from Baseline to Follow-up Visit 2. (*Id.* at UTC\_PH-ILD\_010602 (Efficacy Parameters).) It also found that NT-proBNP

- k. Claim 17: “The method of claim 1, wherein said administering increases a 6 minutes walk distance of the patient by at least 10 m after 8 weeks of the administering.”**

For the reasons explained in Asserted Claim 2 above, a POSA would have been motivated to combine the '793 patent, Agarwal 2015, and Saggar 2014 and would have had a reasonable expectation of achieving the limitation recited in Asserted Claim 17 of the '327 patent.

- l. Claim 18: “The method of claim 1, wherein said administering increases a 6 minutes walk distance of the patient by at least 15 m after 12 weeks of the administering.”**

For the reasons explained in Asserted Claim 2 above, a POSA would have been motivated to combine the '793 patent, Agarwal 2015, and Saggar 2014 and would have had a reasonable expectation of achieving the limitation recited in Asserted Claim 18 of the '327 patent.

- m. Claim 19: “The method of claim 1, wherein said administering increases a 6 minutes walk distance of the patient by at least 15 m after 16 weeks of the administering.”**

For the reasons explained in Asserted Claim 2 above, a POSA would have been motivated to combine the '793 patent, Agarwal 2015, and Saggar 2014 and would have had a reasonable expectation of achieving the limitation recited in Asserted Claim 19 of the '327 patent.

**C. Asserted Claims 1–11 and 14–19 of the '327 Patent Are Rendered Obvious by the '793 Patent in Combination with Faria-Urbina 2018 and Saggar 2014**

**1. Motivation to Combine the '793 Patent in Combination with Faria-Urbina 2018 and Saggar 2014 with a Reasonable Expectation of Success.**

A POSA would have been motivated to combine the teachings of the '793 patent with Faria-Urbina 2018 and Saggar 2014 and would have had a reasonable expectation of success in combining these teachings. All three disclose the treatment of PH-ILD with treprostinil. Both the '793 patent and Faria-Urbina 2018 specifically describe treating PH-ILD patients with inhaled treprostinil according to similar dosing schemes (i.e., between 15 and 90 µg in 3 breaths

administered several times per day). (*See* Faria-Urbina 2018 at UTC\_PH-ILD\_009937 (Treatment regimen and follow-up).)

As discussed in Section III.A.3 above, POSAs were already administering inhaled treprostinil to PH-ILD patients and therefore had motivation to combine the teachings of prior art references long before April 2020. At least one of the steering committee members for the INCREASE Study, Dr. Waxman, was motivated to combine the prior art method of treating inhaled treprostinil from the '793 patent with the use of inhaled treprostinil to improve exercise capacity and 6MWD in PH-ILD in Faria-Urbina 2018. (Nathan Dep. Tr. at 206:9-14; 218:10-221:20; 222:25-224:5.) Additionally, the INCREASE Study cites to Faria-Urbina 2018 as motivation for conducting the study. (*See* Waxman 2021 at UTC\_PH-ILD\_010791, UTC\_PH-ILD\_010799.) Furthermore, the co-steering committee members did not doubt that the INCREASE Study would be successful and even UTC's CEO seemed optimistic when asked about the rationale for the INCREASE Study. (*See* Section V.B.1, *supra*, *see also* Nathan Dep. Tr. at 41:12-23, 44:6-11, 159:14-160:25, 202:14-206:7, 222:25-224:5, 232:2-9; UTC 2018 Earnings Call at 10.)

A POSA would have been further motivated to combine Saggar 2014 with the '793 patent and Faria-Urbina 2018 since all three publications describe the use of treprostinil to treat PH, including PH-ILD. Additionally, Faria-Urbina 2018 and Saggar 2014 both disclosed improvements in six-minute walk distance and FVC. While the improvements in Saggar 2014 were due to parenteral treprostinil, a POSA would have been motivated to determine if the benefits in PH-ILD patients treated with parenteral treprostinil would be seen when administering inhaled treprostinil to a patient with PH-ILD instead. Based on the improvements seen in Saggar 2014, a POSA would have had a reasonable expectation of success when combining Saggar 2014 with the '793 patent and Agarwal 2015 to achieve the claimed invention of the '327 patent.

**2. Claim 1 of the '327 Patent Is Obvious Over the '793 Patent in Combination with Faria-Urbina 2018 and Saggar 2014**

- a. Claim 1[a]: “A method of improving exercise capacity in a patient having pulmonary hypertension associated with interstitial lung disease, comprising”**

A POSA would have been motivated to combine the teachings of the '793 patent with Faria-Urbina 2018 and Saggar 2014 to arrive at Asserted Claim limitation 1[a] and would have had a reasonable expectation of success in combining these teachings. For all of the reasons explained in Section IV.A above, the '793 patent discloses a method of treatment for PH, which includes PH-ILD. Additionally, Faria-Urbina 2018 describes a retrospective study in patients with Group 3 PH, including interstitial lung disease, who were treated with inhaled treprostинil. (Faria-Urbina 2018 at UTC\_PH-ILD\_009937 (Treatment regimen and follow-up).) The results of Faria-Urbina 2018 showed “improved (or maintained) functional class[,]” “19 improved SpO<sub>2</sub>; 10 had follow-up with 6MWT—all of them showing improvement in distance walked[.]” (*Id.* at UTC\_PH-ILD\_009939.) On the basis of the data, the study concludes that “patients with Group 3 PH treated with [inhaled treprostинil], therapy with [inhaled treprostинil] significantly improved WHO-FC and 6MWT distance” (*id.* (Discussion)) and “the results suggest that [inhaled treprostинil] is safe in patients with Group 3 PH and evidence of pulmonary vascular remodeling in terms of functional class, gas exchange, and exercise capacity.” (*Id.* at UTC\_PH-ILD\_009936 (Abstract, Conclusions).) Based on the results, the authors concluded that inhaled treprostинil was safe in Group 3 PH patients and showed evidence of improving exercise capacity in those patients. (*Id.*)

A POSA would have been motivated to combine the '793 patent's method of treatment with Faria-Urbina 2018's disclosure of improvements in exercise capacity following treprostинil administration in PH-ILD patients to arrive at Asserted Claim 1[a] which recites “[a] method of improving exercise capacity in a patient having pulmonary hypertension associated with interstitial

lung disease[.]” Because the results in Faria-Urbina 2018 demonstrated suggested improvements in exercise capacity, a POSA would have had a reasonable expectation of success when combining the ’793 patent with Faria-Urbina 2018.

- b. **Claim 1[b]-[d]: “administering by inhalation to the patient having pulmonary hypertension associated with interstitial lung disease an effective amount of at least 15 micrograms up to a maximum tolerated dose of treprostinil or a pharmaceutically acceptable salt thereof in a single administration event that comprises at least 6 micrograms per breath.”**

A POSA would have been motivated to combine the teachings of the ’793 patent with Faria-Urbina 2018 and Saggar 2014 to arrive at Asserted Claim limitations 1[b]-[d] and would have had a reasonable expectation of success in combining these teachings.

As an initial matter, and as explained in Section IV.A.1 above, the ’793 patent discloses Asserted Claim limitations 1[b]-1[d], which recite “administering by inhalation to the patient having pulmonary hypertension associated with interstitial lung disease an effective amount of at least 15 micrograms up to a maximum tolerated dose of treprostinil or a pharmaceutically acceptable salt thereof in a single administration event that comprises at least 6 micrograms per breath.”

A POSA would have been motivated to combine the ’793 patent with Faria-Urbina 2018 since it also discloses these limitations. As described in Section III.B.6 above, Faria-Urbina 2018 discloses the treatment of PH-ILD patients with inhaled treprostinil. Faria-Urbina 2018 also discloses a dosing scheme of three breaths (18 µg) four times daily (72 µg) with “doses [] increased as tolerated by three additional breaths (18 µg) per dosing session every 3–7 days to achieve a dose of at least 9–12 breaths or more ( $\geq 54 \mu\text{g}$ ) four times daily . . . .” (Farina-Urbina 2018 at UTC\_PH-ILD\_009937 (Treatment regimen and follow-up).) Because the publications are in the same field and disclose similar dosing regimens for PH-ILD patients, a POSA would have been motivated to combine the ’793 patent’s method of treatment with the method disclosed in Faria-Urbina 2018’s

to arrive at Asserted Claim limitations 1[b]-[d] and would have had a reasonable expectation of success in doing so.

**3. Dependent Claims 2–11 and 14–19 Are Obvious Over '793 Patent in Combination with Faria-Urbina 2018 and Saggar 2014**

- a. **Claim 2: “The method of claim 1, wherein said administering provides a statistically significant increase of a 6 minutes walk distance in the patient after 8 weeks, 12 weeks, or 16 weeks of the administering.”**

The combination of the '793 patent with Faria-Urbina 2018 and Saggar 2014 make obvious Asserted Claim 2. As described in Section IV.A.2.a above, the '793 patent inherently discloses the limitations of Asserted Claim 2. A POSA would have understood that administering treprostinil as described in the '793 patent would show a statistically significant increase in 6-minute walk distance in a patient after 8 weeks, 12 weeks, or 16 weeks of administering based on the 2017 INCREASE Study Description. (*See* 2017 INCREASE Study Description at 10 (Arms and Interventions; Outcome Measures); Waxman 2021 at UTC\_PH-ILD\_010796 (Figure 2).)

Faria-Urbina 2018 reported that out of the 22 Group 3 PH patients eligible for follow-up analysis, the ten patients that had a follow-up with the six-minute walk test after three months of treatment showed significant improvements in their six-minute walk distances.<sup>23</sup> (Faria-Urbina 2018 at UTC\_PH-ILD\_009938, UTC\_PH-ILD\_009940). Table 2 shows that the average increase in 6MWD was 65 meters (reporting a baseline of  $243 \pm 106$  meters, a follow-up score of  $309 \pm 109$  meters, and a p value of 0.022). (*Id.* UTC\_PH-ILD\_009940 (Table 2).)

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<sup>23</sup> Note that on UTC\_PH-ILD\_009939, the authors write that only “10 had follow-up with 6MWT—all of them showing improvement in the distance walked[.]” However, the authors report that there were 11 patients who took the 6MWT at the follow-up on UTC\_PH-ILD\_009938, in Table 2 on UTC\_PH-ILD\_009940, and in Fig. 3 on UTC\_PH-ILD\_009940. To err on the conservative side, Liquidia has chosen to assume that at least 10 patients took the follow-up 6MWT for the purposes of these invalidity contentions.

Saggar 2014 also discloses a statistically significant improvement in 6-minute walk distance after 12 weeks. Table 2 of Saggar 2014 shows that there was a mean improvement of 59 meters in patients' 6-minute walk distance after 12 weeks of treprostinil therapy ( $p<0.001$ ). (Saggar 2014 at LIQ\_PH-ILD\_00000228-229.) A POSA would have been motivated to combine Faria-Urbina 2018 and Saggar 2014 with the '793 patent since all three prior art references describe the use of treprostinil to treat PH, including PH-ILD, and show an improvement in 6MWD to arrive at the limitation recited in Asserted Claim 2 of the '327 patent and would have had a reasonable expectation of success in doing so.

**b. Claim 3: “The method of claim 1, wherein said administering increases a 6 minutes walk distance of the patient by at least 10 m after 8 weeks, 12 weeks, or 16 weeks of the administering.”**

Based on the reasons explained for Asserted Claim 2 above, a POSA would have been motivated to combine the '793 patent, Faria-Urbina 2018, and Saggar 2014 and would have a reasonable expectation of success in achieving the limitation in Asserted Claim 3 of the '327 patent.

**c. Claims 4 and 5: “The method of claim 1, wherein said administering provides a statistically significant reduction of a plasma concentration of NT-proBNP in the patient after 8 weeks, 12 weeks, or 16 weeks of the administering[]” and “[t]he method of claim 1, wherein said administering reduces a plasma concentration of NT-proBNP in the patient by at least 200 pg/ml after 8 weeks, 12 weeks, or 16 weeks of the administering.”**

A POSA would have been motivated to combine the teachings of the '793 patent with Faria-Urbina 2018 and Saggar 2014 to arrive at the limitations in Asserted Claims 4 and 5 and would have had a reasonable expectation of success in combining these teachings. As explained above in Section IV.A.2.c, the '793 patent inherently discloses Asserted Claim 4 because it uses the same dosing regimen employed in the INCREASE Study (both describe  $> 15 \mu\text{g}$  including 54  $\mu\text{g}$ , in multiple breaths including 9 breaths, more than one time per day with 6  $\mu\text{g}$  per breath) where

NT-proBNP levels dropped 203.4 pg/ml by 8 weeks into the study. (See Section III.B.1, *supra*; Waxman 2021 at UTC\_PH-ILD\_010792, UTC\_PH-ILD\_010816 (Figure S4).) The '793 patent also reports a reduction of at least 200 pg/ml after 8 weeks as described in Section IV.A.2.d, above.

In Saggar 2014, patients treated with parenteral treprostinil saw their BNP (brain natriuretic peptide) levels fall from 558 pg/ml to 228 pg/ml, a difference of 330 pg/ml, after 12 weeks, which would give a POSA a reasonable expectation of success in seeing a reduction of at least 200 pg/ml after at least 8 weeks when administering inhaled treprostinil. (Saggar 2014 at LIQ\_PH-ILD\_00000230 (Tbl. 4).) Because BNP and NT-proBNP are both good indicators of disease severity in PH, there is a positive correlation between the two biomarkers, and there is no clear advantage in using one biomarker over the other, a POSA would have understood that Saggar 2014's statistically significant reduction of BNP levels is equivalent to a statistically significant reduction in NT-proBNP levels.<sup>24</sup> A POSA would understand the positive correlation between the two biomarkers and would be motivated to combine Saggar 2014 with Parikh 2016 with the '793 patent to achieve Asserted Claim 4 and would have had a reasonable expectation of success in doing so.

A POSA would be motived to combine the teachings of Faria-Urbina 2018 with the '793 patent and Saggar 2014 to determine the effects of inhaled treprostinil on NT-proBNP since all three publications describe improvements in 6MWD and hemodynamic parameters as a result of using treprostinil to treat PH, including PH-ILD. By combining Saggar 2014 with Faria-Urbina 2018 and the '793 patent, a POSA would have expected patients treated with inhaled treprostinil

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<sup>24</sup> See Robert P. Frantz et al, *Baseline NT-proBNP correlates with change in 6-minute walk distance in patients with pulmonary arterial hypertension in the pivotal inhaled treprostinil study TRIUMPH-1*, 31 J. Heart & Lung Transplantation 811, 812 (2012) (available at [https://www.jhltonline.org/article/S1053-2498\(12\)01076-5/fulltext](https://www.jhltonline.org/article/S1053-2498(12)01076-5/fulltext)) (LIQ\_PH-ILD\_00101518).

to show a similar reduction in their NT-proBNP (brain natriuretic peptide) levels. Thus, Asserted Claims 4 and 5 of the '327 patent are invalid as obvious.

**d. Claim 6: “The method of claim 1, wherein said administering provides a statistically significant reduction of at least one exacerbations of the interstitial lung disease.”**

The '793 patent in combination with Faria-Urbina 2018 and Saggar 2014 discloses Asserted Claim 6. As explained above in Section IV.A.2.e, the '793 patent discloses “wherein said administering provides a statistically significant reduction of at least one exacerbations of the interstitial lung disease.”

Faria-Urbina 2018 further discloses an improvement in exacerbations. It discloses that 21 out of the 22 patients in the study “improved (or maintained) functional class[,]” “19 improved SpO<sub>2</sub>; 10 had follow-up with 6MWT—all of them showing improvement in distance walked[.]” (Faria-Urbina 2018 at UTC\_PH-ILD\_009939.) On the basis of the data, the study concludes that “patients with Group 3 PH treated with [inhaled treprostинil], therapy with [inhaled treprostинil] significantly improved WHO-FC and 6MWT distance.” (*Id.* (Discussion).) and “the results suggest that “[inhaled treprostинil] is safe in patients with Group 3 PH and evidence of pulmonary vascular remodeling in terms of functional class, gas exchange, and exercise capacity.” (*Id.* at UTC\_PH-ILD\_009936(Abstract, Conclusions).) Because Faria-Urbina 2018 describes an overall benefit to the patients, a POSA would have expected that the patients also showed an improvement in PH-ILD exacerbations. A POSA would have also understood that exacerbations are associated with deterioration in functional capacity, while in contrast, Faria-Urbina 2018 reports that patients had improvements on these parameters.

Saggar 2014 disclosed improvements in FVC and 6MWD, along with dyspnea and quality of life which were measured using the University of California San Diego Shortness of Breath (UCSD SOB) questionnaire and Short Form Health Survey respectively. (Saggar 2014 at

LIQ\_PH-ILD\_00000228-229.) The authors reported a statistically significant improvement in each of these metrics. In particular, patients responding to questions in the Short Form Health Survey reported improvements in their physical functioning, bodily pain, general health, and vitality. (Saggar 2014 at LIQ\_PH-ILD\_00000229.) Because Saggar 2014 describes an overall benefit to patients, and in particular describes improvements in functional capacity, including patients self-reported improvements in physical health, a POSA would have understood that the patients likely had improvements in PH-ILD exacerbations.

A POSA would have been motivated to combine the '793 patent with Faria-Urbina 2018 and Saggar 2014 since all three publications describe the use of treprostinil to treat PH, including PH-ILD, and show improvements in functional capacity, which inversely correlates with exacerbations. By combining the disclosures of these three references, a POSA would have had a reasonable expectation of success in achieving the limitation of Asserted Claim 6 of the '327 patent.

- e. **Claims 7 and 8:** “The method of claim 1, wherein said administering provides a statistically significant reduction of clinical worsening events due to the interstitial lung disease[]” and “[t]he method of claim 7, wherein the clinical worsening events comprise at least one of hospitalization for cardiopulmonary indication and a decrease in a 6-minute walk distance by more than 15% compared a baseline 6-minute walk distance prior to the administering.”

The '793 patent in combination with Faria-Urbina 2018 and Saggar 2014 discloses Asserted Claims 7 and 8. Sections IV.A.2.f and IV.A.2.g above discusses how the '793 patent discloses “a statistically significant reduction of clinical worsening events due to the interstitial lung disease” and “wherein the clinical worsening events comprise at least one of hospitalization for cardiopulmonary indication and a decrease in a 6-minute walk distance by more than 15% compared a baseline 6-minute walk distance prior to the administering.” For those same reasons, the '793 patent in combination with Faria-Urbina 2018 and Saggar 2014 discloses Asserted Claims

7 and 8. Moreover, because the results in Faria-Urbina 2018 and Saggar 2014 show improvements that inversely relate to clinical worsening events (notably an increase in six-minute walk distance rather than a decrease) a POSA would expect to have reasonable success in seeing a statistically significant reduction in clinical worsening events when treating a patient with PH-ILD using the dosing regimens in Faria-Urbina 2018 and Saggar 2014. Accordingly, Asserted Claims 7 and 8 are invalid as obvious.

**f.      Claims 9 and 10:** “**The method of claim 1, wherein said administering provides a statistically significant improves of forced vital capacity (FVC) in the patient after 8 weeks, 12 weeks, or 16 weeks of the administering[]” and “[t]he method of claim 9, wherein said administering improves the forced vital capacity (FVC) in the patient by at least 20 ml after 8 weeks, 12 weeks, or 16 weeks of the administering.”**

Asserted Claim 9 requires that “said administering provides a statistically significant improves [sic] of forced vital capacity (FVC) in the patient after 8 weeks, 12 weeks, or 16 weeks of the administering.” Claim 10 requires that “said administering improves the forced vital capacity (FVC) in the patient by at least 20 ml after 8 weeks, 12 weeks, or 16 weeks of the administering.” A POSA would have been motivated to combine the teachings of the ’793 patent with Faria-Urbina 2018 and Saggar 2014 to arrive at Asserted Claims 9 and 10 and would have had a reasonable expectation of success in combining these teachings.

As explained in Sections IV.A.2.h and IV.A.2.i above, the ’793 patent discloses Asserted Claims 9 and 10. Further, the ’793 patent in combination with Faria-Urbina 2018 and Saggar 2014 discloses these claims. With respect to the improvement in FVC, 20 mL of lung volume is approximately 1–2 % of lung volume. While not statistically significant, Faria-Urbina 2018 does disclose an improvement of 8% in FVC % predicted after a period of three months (change from  $67\pm26$  baseline to  $59\pm22$  follow-up with a p value of 0.12) which at the very least discloses FVC as a metric for evaluating the effects of inhaled treprostinil in PH-ILD patients. (Faria-Urbina

2018 at UTC\_PH-ILD\_009940.)

On the other hand, Saggar 2014 discloses a 1% improvement in FVC predicted %. (Saggar 2014 at LIQ\_PH-ILD\_00000228 (Tbl. 2).) This 1% change is comparable to the 1.1% change described in the INCREASE Study which the INCREASE Study reports as a significant improvement in FVC. (Waxman 2021 at UTC\_PH-ILD\_010825 (Tbl. S6).) Thus, to the extent the INCREASE Study and the '327 patent report that a 1.1% effect is significant, so too is the improvement reported in Saggar 2014.

A POSA would have been motivated to combine Saggar 2014 with the '793 patent and Faria-Urbina 2018 since all of these publications describe the use of treprostinil to treat PH, including PH-ILD. Moreover, a POSA would have had a reasonable expectation of success in achieving Asserted Claims 9 and 10 of the '327 patent given the improvement reported in Saggar 2014.

**g. Claims 11 and 14:** “**The method of claim 1, wherein said administering is performed by a pulsed inhalation device[]” and “[t]he method of claim 11, wherein the pulsed inhalation device is a dry powder inhaler comprising a dry powder comprising treprostinil or a pharmaceutically acceptable salt thereof.”**

Asserted Claims 11 and 14 are disclosed by the combination of the '793 patent, Faria-Urbina 2018, and Saggar 2014. Sections IV.A.2.j and IV.A.2.k above discusses how the '793 patent discloses “administering is performed by a pulsed inhalation device” and “the pulsed inhalation device is a dry powder inhaler comprising a dry powder comprising treprostinil or a pharmaceutically acceptable salt thereof.” For those same reasons, the '793 patent in combination with Faria-Urbina 2018 discloses Asserted Claims 11 and 14. Moreover, because dry powder inhalers are smaller and more convenient than nebulizers, a POSA would have been motivated to apply the dry powder inhaler of the '793 patent to the teachings of Faria-Urbina 2018 and Saggar 2014 and would have had a reasonable expectation of success in doing so to achieve Asserted

Claims 11 and 14 of the '327 patent.

- h. **Claim 15: “The method of claim 1, wherein the effective amount of treprostinil or a pharmaceutically acceptable salt administered to the patient in a single inhalation administration event is from 15 µg to 100 µg.”**

A POSA would have been motivated to combine the teachings of the '793 patent with Faria-Urbina 2018 and Saggar 2014 to arrive at Asserted Claim 15 and would have had a reasonable expectation of success in combining these teachings.

Claim 15 is disclosed by the combination of the '793 patent, Faria-Urbina 2018, and Saggar 2014. As explained in section IV.A.2.1 above, the '793 patent discloses Asserted Claim 15. A POSA would understand that a “single event dose” is equivalent to a “single inhalation administration event” because both phrases refer to a single instance of administering inhaled treprostinil. From the specification, a POSA would have understood that 15 µg to about 100 µg in preferably 3, 2, or 1 breaths would be anywhere from 5 µg to 100 µg per breath (i.e., 15 µg/3 breaths to 100 µg/1 breath), which discloses Asserted Claim 15. (*See also* '793 patent at UTC\_PH-ILD\_009791 (7:55-59; 7:60-64).)

Furthermore, Faria-Urbina 2018 discloses a dosing regimen of three breaths (18 µg) four times daily (72 µg) with “doses [] increased as tolerated by three additional breaths (18 µg) per dosing session every 3–7 days to achieve a dose of at least 9–12 breaths or more ( $\geq 54 \mu\text{g}$ ) four times daily . . .” (Faria-Urbina 2018 at UTC\_PH-ILD\_009937 (Treatment regimen and follow-up).) Based on the state of the art in 2018 (including the Tyvaso® Label and the fact that physicians regularly dosed patients with 3-breaths 4x daily to a goal of 9-12 breaths as tolerated), a POSA would have expected that three breaths four times daily refers to the known dosing regimen for Tyvaso®, which in 2018 started at 3 breaths 4 times daily with approximately 6 µg of treprostinil per breath. Therefore Faria-Urbina 2018 discloses an effective amount of treprostinil or a pharmaceutically acceptable salt in the amount of 18-72 µg.

Because the '793 patent and Faria-Urbina 2018 describe the use of treprostinil to treat PH, including PH-ILD, a POSA would have been motivated to combine them to achieve the limitations of Asserted Claim 15 of the '327 patent and would have a reasonable expectation of success in doing so.

i. **Claim 16: “The method of claim 15, wherein the single inhalation administration event does not exceed 15 breaths by the patient.”**

The '793 patent in combination with Faria-Urbina 2018 discloses Asserted Claim 16. The '793 patent discloses that administering treprostinil in a single event can occur “in 20 breaths or less, or in 10 breaths or less, or than 5 breaths or less” thereby anticipating Asserted Claim 16. ('793 patent at UTC\_PH-ILD\_009791 (7:60-64).) It further discloses that treprostinil is preferably administer in 3, 2, or 1 breaths, which do not exceed the 15 breaths limitation covered by Asserted Claim 16. (*Id.*)

Faria-Urbina 2018 discloses administering a maximum of 12 breaths per single inhalation administration event. (Faria-Urbina 2018 at UTC\_PH-ILD\_009937 (Treatment regimen and follow-up).) While it suggests that a patient could be administered more than 12 breaths, it does not disclose any patient being treated with a higher dosage than 12 breaths per single administration event. (*Id.*)

A POSA would have been motivated to combine the '793 patent and Faria-Urbina 2018 to achieve the disclosure of Asserted Claim 16 and would have a reasonable expectation of success because they both describe the use of treprostinil to treat PH, including PH-ILD as well as similar dosing regimens.

- j. **Claim 17: “The method of claim 1, wherein said administering increases a 6 minutes walk distance of the patient by at least 10 m after 8 weeks of the administering.”**

Based on the reasons explained for Asserted Claim 2 above, a POSA would have been motivated to combine the '793 patent, Faria-Urbina 2018, and Saggar 2014 and would have a reasonable expectation of success in achieving the limitation in Asserted Claim 17 of the '327 patent.

- k. **Claim 18: “The method of claim 1, wherein said administering increases a 6 minutes walk distance of the patient by at least 15 m after 12 weeks of the administering.”**

Based on the reasons explained for Asserted Claim 2 above, a POSA would have been motivated to combine the '793 patent, Faria-Urbina 2018, and Saggar 2014 and would have a reasonable expectation of success in achieving the limitation in Asserted Claim 18 of the '327 patent.

- l. **Claim 19: “The method of claim 1, wherein said administering increases a 6 minutes walk distance of the patient by at least 15 m after 16 weeks of the administering.”**

Based on the reasons explained for Asserted Claim 2 above, a POSA would have been motivated to combine the '793 patent, Faria-Urbina 2018, and Saggar 2014 and would have a reasonable expectation of success in achieving the limitation in Asserted Claim 19 of the '327 patent.

**D. Asserted Claims 1–11 and 14–19 of the '327 Patent Are Rendered Obvious by the '793 Patent in Combination with Parikh 2016 and Saggar 2014**

**1. Motivation to Combine the '793 Patent in Combination with Parikh 2016 and Saggar 2014 with a Reasonable Expectation of Success.**

A POSA would have been motivated to combine the teachings of the '793 patent with Parikh 2016 and Saggar 2014 and would have had a reasonable expectation of success in combining these teachings. As an initial matter, a POSA would have been motivated to combine

Messrs. Maebius and Snader knew this information filled the gaps of the alleged deficiencies of the prior art cited during prosecution. Accordingly, Mr. Maebius and UTC, including Mr. Snader, had a duty to bring to the Examiner's attention the related '793 patent litigation and IPR submissions to the PTO during prosecution of the '327 patent.

Disclosing, albeit buried among over 400 references, the '793 patent and the Petition for an IPR of the '793 patent does not excuse Mr. Maebius and UTC, including Mr. Snader, from disclosing other related litigation or additional information from the '793 IPR because the absence of this information prevented the Patent Office from appreciating the scope and significance of the '793 patent during the prosecution of the '327 patent. *Graphics Props. Holdings, Inc. v. Google, Inc.*, Nos. 12-1394-LPS, -1397-LPS, 2014 WL 6629021, at \*2 (D. Del. Nov. 20, 2014) (Court dismissed argument that the patentee had no need to disclose further litigation after disclosing the underlying appealed district court order because the Federal Circuit opinion contained relevant statements not in the district court opinion).

Mr. Maebius's and UTC's, including Mr. Snader's, intentional withholding of material information constituted a breach of the duty of candor owed to the USPTO with a specific intent to deceive and constitutes inequitable conduct that renders all of the claims of the '327 patent unenforceable.

## **VIII. CONCLUSION**

Based upon the information presently available to Liquidia, and based upon Liquidia's initial understanding of the scope and construction of the Asserted Claims of the '327 patent, and of UTC's apparent positions concerning the scope and construction of the Asserted Claims of the '327 patent, the Asserted Claims of the '327 patent are invalid at least for the reasons set forth above and based on the production that will accompany these First Amended Invalidity

**CERTIFICATE OF SERVICE**

I certify that I caused copies of the foregoing document to be served on October 30, 2024 upon the following in the manner indicated:

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# EXHIBIT 3

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS )  
CORPORATION, )  
Plaintiff, )  
v. ) C.A. No. 23-975-RGA-SRF  
LIQUIDIA TECHNOLOGIES, INC., ) [REDACTED]  
Defendant. )

**DEFENDANT LIQUIDIA TECHNOLOGIES, INC.'S  
FINAL INVALIDITY CONTENTIONS**

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[REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Thus, none of the claims of the '327 patent are entitled to the April 17, 2020 priority date of the '810 Provisional.<sup>2</sup>

**1. The Claims of the '327 Patent are Anticipated by UTC's February 24, 2020 Press Release**

As discussed above, [REDACTED]

[REDACTED]. However, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Therefore, the '327 patent is not entitled to an April 17, 2020 priority date because the complete results of the INCREASE study were not disclosed in the provisional application.<sup>3</sup> Because the

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<sup>2</sup> Should UTC change its position and claim a priority date for the '327 patent post-dating the currently alleged April 17, 2020 priority date, Liquidia reserves the right to amend its invalidity contentions to add additional prior art references that post-date the April 17, 2020 priority date. Liquidia's reservation of rights does not constitute an admission that the '327 patent is entitled to the April 17, 2020 priority date.

<sup>3</sup> UTC's Amended First Supplemental Response to Liquidia's First Set of Interrogatories, dated November 19, 2024, provides a chart attempting to align the '327 patent's claim limitations and

'327 patent is not entitled to an April 17, 2020 priority date, additional prior art renders the Asserted Claims invalid for anticipation and obviousness, including UTC's February 24, 2020 press release title "United Therapeutics Announces INCREASE Study of Tyvaso® Meets Primary and All Secondary Endpoints." See (<https://www.prnewswire.com/news-releases/united-therapeutics-announces-increase-study-of-tyvaso-meets-primary-and-all-secondary-endpoints-301009562.html> ("Feb. 24, 2020 Press Release").)

UTC's press release specifically discloses that the INCREASE trial exhibited "Tyvaso increas[ing] six-minute walk distance by 21 meters versus placebo (p=0.0043, Hodges-Lehmann estimate) after 16 weeks of treatment." (*Id.*) [REDACTED]

[REDACTED] The press release also reported that "[s]ignificant improvements were also observed in each of the study's secondary endpoints including reduction in the cardiac biomarker NT-proBNP, time to first clinical worsening event, change in peak 6MWD at Week 12, and change in trough 6MWD at week 15." (Feb. 24, 2020 Press Release.)

The press release concludes with a section on the details of the INCREASE study, disclosing that:

- "INCREASE was a phase III, multicenter, randomized, double-blinded, placebo-controlled, 16-week, parallel group study of Tyvaso in patients with pulmonary hypertension associated with interstitial lung disease. Enrollment into the study was completed in August 2019 with a total of 326 patients. Patients were randomized in a 1:1 Tyvaso (n=163) or placebo (n=163)." (*Id.*)

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the alleged support found in the provisional application's specification. (See UTC's Amended First Supplemental Response to Liquidia's First Set of Interrogatories, 58-97.) However, UTC's chart fails to show that the '327 patent's provisional application disclosed the INCREASE study results on exercise capacity, NT-proBNP, and clinical worsening.

- “The primary endpoint primary endpoint was to evaluate the change in 6-minute walk distance (6MWD) measured at peak exposure from Baseline to Week 16.” (*Id.*)
- “Secondary objectives of the study included:
  - Change in plasma concentration of N-terminal pro-brain natriuretic peptide (NT-proBNP) from Baseline to Week 16
  - Time to clinical worsening calculated as the time from randomization until one of the following criteria are met:
    - Hospitalization due to a cardiopulmonary indication
    - Decrease in 6MWD >15% from Baseline directly related to disease under study, at two consecutive visits, and at least 24 hours apart
    - Death (all causes)
    - Lung transplantation
  - Change in peak 6MWD from Baseline to Week 12
  - Change in trough 6MWD from Baseline to Week 15.”

(*Id.*) Based on this disclosure, the press release would thus render at least Claims 1-8, 15-19 of the ’327 patent invalid as anticipated, either expressly or inherently, under 35 U.S.C. § 102. (*See infra* Section VI.B-C.) The press release, in combination with Saggar 2014, would also render Claims 9-10 of the ’327 patent obvious under 35 U.S.C. § 103. (*See infra* Sections VII.G.3.h-i & VI.H.3.h-i.) The press release, in combination with the ’793 patent, would finally render Claims 11 and 14 of the ’327 patent obvious under 35 U.S.C. § 103. (*See infra* Sections VII.A.2.d.)

### C. The ’327 Patent is Invalid Because of Improper Inventorship

“A patent is invalid if more or less than the true inventors are named.” (*Trovan, Ltd. v. Sokymat SA, Irori*, 299 F.3d 1292, 1301 (Fed. Cir. 2002).) The ’327 patent is invalid because it does not properly name all inventors. “Conception is the touchstone of inventorship,” and the ’327

patent improperly omits at least Dr. Aaron Waxman as an inventor, despite him conceiving the INCREASE study, which is the clinical trial underlying the '327 patent. (*Id.*, 299 F.3d at 1302 (citations omitted).) “To be a joint inventor, one must: (1) contribute in some significant manner to the conception or reduction to practice of the invention, (2) make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art.” (*Dana-Farber Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd.*, 964 F.3d 1365, 1371 (Fed. Cir. 2020).) Whether Dr. Waxman knew the INCREASE study would be successful is immaterial. “An inventor need not know, however, that an invention will work for its intended purpose in order for conception to be complete, as verification that an invention actually works is part of its reduction to practice.” (*Eli Lilly and Co.*, 376 F.3d at 1372 (citing *Burroughs Wellcome*, 40 F.3d at 1228).)

[REDACTED]

[REDACTED] UTC and Dr. Waxman even represented to the FDA, in a letter dated November 15, 2017, that Dr. Waxman’s work “has laid the basis for [the

INCREASE trial's] concepts" and that "as we have seen in our preliminary studies, it is anticipated that patients with ILD-PH may be more likely to benefit from prostacyclin therapy such as treprostinil." (UTC\_LIQ00104555.)

The image shows a single page of paper with all its content completely obscured by a series of thick, solid black horizontal bars. There are approximately 20 such bars, spaced evenly down the page, creating a pattern of alternating black and white horizontal stripes. The black bars are thick enough to completely cover any text or other markings that might have been present on the original document.

A series of eight horizontal black bars of varying lengths, decreasing from left to right. The first seven bars are of equal length, while the eighth bar is significantly longer than the others.

[REDACTED], for the reasons discussed above, has clearly contributed in a significant manner to the conception of the INCREASE trial, has made a contribution to the INCREASE trial that is not insignificant in quality, and did more than merely explain to the real inventors well-known concepts and/or the current state of the art, and is thus a joint inventor of the '327 patent. (*Dana-Farber*, 964 F.3d at 1371.) Because the '327 patent improperly omits proper inventors, including at least [REDACTED], the '327 patent is invalid for improper inventorship. (*Trovan*, 299 F.3d at 1301.)

### III. THE CLAIMS OF THE '327 PATENT ARE INVALID BY PRIOR PUBLIC USE

**A. Prior Public Use of Tyvaso® to Treat PH-ILD Invalidates Claims 1-11 and 15-19 of the '327 Patent**

The Asserted Claims are invalid because the claimed invention was used in the public before the effective filing date of the '327 patent. Under 35 U.S.C. § 102(a)(1), a patent is invalid if “the claimed invention was . . . in public use . . . or otherwise available to the public before the effective filing date of the claimed invention. The “public use bar” of 35 U.S.C. § 102 is triggered if, more than one year before the filing date of the application, the invention was (1) “in public use” and (2) “ready for patenting.” (*See Barry v. Medtronic, Inc.*, 914 F.3d 1310, 1320-21 (Fed. Cir. 2019); *see also* 35 U.S.C. §§ 102(a)(1), 102(b)(1).) In assessing whether an invention is “in

public use,” courts consider whether the use was (a) accessible to the public; or (b) was commercially exploited. (*See Dey, L.P. v. Sunovion Pharms., Inc.*, 715 F.3d 1351, 1355 (Fed. Cir. 2013).) An invention is ready for patenting if there is proof that, prior to the priority date of the patent, the invention was sufficiently disclosed such that a POSA would be able to practice the invention. (*See Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 65, 67-68 (1998).)

[REDACTED]

Dr. Martine

Rothblatt, UTC’s CEO, publicly stated to investors that

[B]oth through the effort of our medical affairs group over the years in supporting investigator-sponsored studies and through the ***kindness and generosity of certain payers around the country*** who have gone ahead and upon the initiative of their physicians, ***were able to enable some WHO Group III patients to benefit*** [from Tyvaso and], there were unmistakable signals the some of the leading physicians in the field[,] I called out one of them on the call, Dr. Waxman, but there are many others, who said to UT, “***This drug works.***”

(UTC 2018 Earnings Call (LIQ\_PH-ILD\_00000001) at LIQ\_PH-ILD\_00000010 (emphasis added).) In other words, in 2018, UTC itself stated that the claimed invention was in public use because it was both (a) accessible to the public (“some WHO Group III patients to benefit”) and (b) commercially exploited (“through the kindness and generosity of certain payers around the

country . . . enable[d]" PH-ILD patients to benefit). The claimed invention was ready for patenting as physicians were, according to UTC's public statement, able to practice the invention by prescribing Tyvaso® to patients with WHO Group III patients. During the 2018 earnings call, Dr. Martine Rothblatt again confirmed that the claimed invention was accessible to the public by stating

In fact, they believe that this drug works even better in that indication than in the Group I indication in terms of, at least, the exercise ability that *they saw in their patients*, discounting any placebo effects that might be involved. So *with that kind of data, some of which has been presented in posters* and maybe even publications -- I don't know, but *I've definitely seen posters*, we went ahead and then had the statistics to power of the study for statistical significance, the one in the ILD population and the other in the COPD population, which are 2 distinct populations.

(*Id.* (emphasis added).)

Numerous physicians have confirmed that the claimed invention of the '327 patent was in public use and ready for patenting well before the effective filing date. Dr. Channick confirmed that physicians, including himself, were regularly prescribing inhaled treprostinil off-label to PH-ILD patients long before the April 2020 priority date of the '327 patent and before Tyvaso® was approved for the treatment of PH-ILD.<sup>4</sup> (D.I. 54 ("Channick Decl.") at ¶52.) Dr. Channick explained that he had started prescribing Tyvaso® to PH-ILD patients almost immediately after it was approved in 2009, and that he followed the dosing regimen on the label. (*Id.*) Even UTC's expert, Dr. Nathan, acknowledged that he likely used inhaled treprostinil off-label to treat PH-ILD

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<sup>4</sup> A 2015 survey of 30 U.S. pulmonary vascular disease centers used PAH therapy in patients with non-group 1 PH, including treprostinil. (A. W. Trammell, et al., *Use of pulmonary arterial hypertension-approved therapy in the treatment of non-group 1 pulmonary hypertension at US referral centers*, Pulm. Circ. 5(2):356-63 (2015) (LIQ\_PH-ILD\_00002539) ("Trammel 2015").) In 2017, the Giessen PH registry showed that the majority of WHO Group 3 patients, including PH-ILD patients, were on PAH therapies. (H. Gall, et al., *The Giessen Pulmonary Hypertension Registry: Survival in pulmonary hypertension subgroups*, J. Heart Lung Transplant. 36(9):957-67 (2017) (LIQ\_PH-ILD\_00001617) ("Gall 2017") at 962 (Tbl. 2).)

patients. (See Nathan Dep. Tr. at 88:19-89:21, 92:15-20, 96:6-8.) [REDACTED]  
[REDACTED]

[REDACTED] Thus, well before the priority date, the claimed invention (1) was “in public use” because (a) it was accessible to the public as doctors were regularly prescribing it to patients with PH-ILD, *and* (b) it was being commercially exploited as payers were willing to enable PH-ILD patients to benefit from Tyvaso®, in addition to physicians enabled their PH-ILD patients to be reimbursed for treatment; and (2) it was “ready for patenting” as physicians were practicing the invention as early as 2009.

**B. Claim 1 of the '327 Patent is Invalid by The Public Use of Tyvaso®**

**1. Claim 1[a]: “A method of improving exercise capacity in a patient having pulmonary hypertension associated with interstitial lung disease, comprising”**

Claim 1[a] of the '327 patent is invalid because the claimed invention was both “in public use” and “ready for patenting” more than one year before the patent’s priority date. Before the April 2020 priority date, and at least as early as 2009, Tyvaso®, along with the 2009 Tyvaso® Label, was publicly available in the United States. Physicians were publicly practicing Claim 1[a] as early as 2009 by prescribing Tyvaso®, following the dosing instructions provided in the Tyvaso® label, to treat patients with PH-ILD and seeing improvements in their exercise capacity. (See, e.g., Channick Decl., ¶ 101; [REDACTED].) Thus, the claimed invention was both in public use and ready for patenting several years before the April 2020 priority date.

**2. Claim 1[b]-[d]: “administering by inhalation to the patient having pulmonary hypertension associated with interstitial lung disease an effective amount of at least 15 micrograms up to a maximum tolerated dose of treprostinil or a pharmaceutically acceptable salt thereof in a single administration event that comprises at least 6 micrograms per breath.”**

Claim limitation 1[b]-[d] of the '327 patent is invalid because the claimed invention was both “in public use” and “ready for patenting” more than one year before the patent’s priority date. According to the 2009 Tyvaso® Label, Tyvaso® was administered in “4 separate treatment sessions each day” in doses of at least “3 breaths [(18 mcg)] per treatment session” where a “single breath of Tyvaso delivers approximately 6 mcg of treprostinil,” and the dosage can be titrated up “to target [a] maintenance dosage of 9 breaths or 54 mcg per treatment session as tolerated.” (2009 Tyvaso® Label at UTC\_PH-ILD\_010693.) According to the 2009 Tyvaso® Label, this dosing regimen was used to improve exercise capacity of PAH patients. This is also the approved dosing regimen for treatment of PH-ILD once Tyvaso® was approved for that indication in 2021.  
[REDACTED]

[REDACTED] Thus, the public use of Tyvaso® by physicians in accordance with the 2009 Tyvaso® Label before the April 2020 priority date allowed for the practice of Claim limitations 1[b]-[d], which constitutes a public-use bar.

**C. Dependent Claims 2-10 are Invalid by The Public Use of Tyvaso®**

Dependent Claims 2-10 of the '327 patent are invalid because the claimed invention was both “in public use” and “ready for patenting” more than one year before the patent’s priority date. As discussed above, the 2009 Tyvaso® Label discloses the same dosing regimen as Asserted Claim 1. Although the 2009 Tyvaso® Label does not literally disclose the limitations of dependent Claims 2-10, such disclosure is not required to meet the public-use bar. Administering Tyvaso® to patients with PH-ILD in accordance with the dosing regimen disclosed in the 2009 Tyvaso® Label will result in patients achieving the limitations disclosed in dependent Claims 2-10. Accordingly, the public use of Tyvaso® to treat patients with PH-ILD in accordance with the 2009 Tyvaso® Label renders dependent Claims 2-10 of the '327 patent invalid.

**D. Dependent Claims 11, 15-19 are Invalid by The Public Use of Tyvaso®**

**1. Claim 11: “The method of claim 1, wherein said administering is performed by a pulsed inhalation device.”**

Dependent Claim 11 of the '327 patent is invalid because the claimed invention was both “in public use” and “ready for patenting” more than one year before the patent’s priority date. Tyvaso®, which utilizes a pulsed inhalation device as its drug delivery mechanism, was publicly used and ready for patenting years before the April 2020 priority date. As discussed above, Tyvaso® was administered using the pulsed inhalation device according to the 2009 Tyvaso® Label, which also discloses a pulsed inhalation device. Specifically, Section 2.1 of the 2009 Tyvaso® Label, titled “Usual Dosage in Adults,” states “Tyvaso is intended for oral

inhalation using the Tyvaso Inhalation System, which consists of the Optineb-ir Model ON-100/7 (an ultrasonic pulsed-delivery device) and its accessories.” (2009 Tyvaso® Label at UTC\_PH-ILD\_010694.) Thus, the Tyvaso Inhalation System (a pulsed inhalation device) and Tyvaso® practice the method described in Claim 11. Furthermore, the Tyvaso Inhalation System and Tyvaso® were in public use and ready for patenting years before the April 2020 priority date. Accordingly, the Tyvaso Inhalation System and Tyvaso®, having been in public use and ready for patenting years before the April 2020 priority date, render dependent Claim 11 invalid.

2. **Claim 15: “The method of claim 1, wherein the effective amount of treprostinil or a pharmaceutically acceptable salt administered to the patient in a single inhalation administration event is from 15 µg to 100 µg.”**

Dependent Claim 15 of the ’327 patent is invalid because the claimed invention was both “in public use” and “ready for patenting” more than one year before the patent’s priority date. Tyvaso® was in public use more than one year before the April 2020 priority date and was administered according to the 2009 Tyvaso® Label, which discloses administering 6 µg per breath, with an initial dose of 3 breaths (resulting in 18 µg) four times daily with a target dose of 9 breaths four times daily. (2009 Tyvaso® Label at UTC\_PH-ILD\_010693; *see also* [REDACTED]

[REDACTED] Further, the 2009 Tyvaso® label indicates the dose can be increased to 9 breaths, resulting in 54 µg per treatment session and 21 µg a day. (*See* 2009 Tyvaso® Label at UTC\_PH-ILD\_010694.) [REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED] Thus, the public use of Tyvaso® by physicians in accordance with the 2009 Tyvaso® Label before the April 2020 priority date allowed for the practice of the dosing range recited in Claim 15, which constitutes a public-use bar.

**3. Claim 16: “The method of claim 15, wherein the single inhalation administration event does not exceed 15 breaths by the patient.**

Dependent Claim 16 of the '327 patent is invalid because the claimed invention was both "in public use" and "ready for patenting" more than one year before the patent's priority date. The 2009 Tyvaso® Label discloses administering 6 µg per breath, with an initial dose of 3 breaths (18 µg) four times daily and a target dose of 9 breaths four times daily. (2009 Tyvaso® Label at UTC\_PH-ILD\_010693.) Because a maximum of 9 breaths in a single inhalation administration event does not exceed 15 breaths by the patient, the public use of Tyvaso® to treat patients with PH-ILD in accordance with the 2009 Tyvaso® Label renders Asserted Claim 16 of the '327 patent invalid

**4. Asserted Claims 17-19 are anticipated by the public use of Tyvaso®**

Dependent Claims 17-19 of the '327 patent are invalid because the claimed invention was both "in public use" and "ready for patenting" more than one year before the patent's priority date. As previously discussed, the 2009 Tyvaso® Label discloses the same dosing regimen as Asserted Claim 1. Although the 2009 Tyvaso® Label does not literally disclose the limitations of dependent Claims 17-19, such disclosure is not required to meet the public-use bar. Administering Tyvaso® to patients with PH-ILD in accordance with the dosing regimen disclosed in the 2009 Tyvaso® Label will result in patients achieving the limitations disclosed in dependent Claims 17-19. Accordingly, the public use of Tyvaso® to treat patients with PH-ILD in accordance with the 2009 Tyvaso® Label renders Asserted Claims 17-19 of the '327 patent invalid.

**IV. THE CLAIMS OF THE '327 PATENT ARE INVALIDATED BY PRIOR PUBLIC SALE<sup>5</sup>**

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<sup>5</sup> For purposes of Liquidia's additional invalidity arguments not based on UTC's February 2020 press release, Liquidia is applying the April 17, 2020 priority date of the '810 Provisional.

**CERTIFICATE OF SERVICE**

I hereby certify that on December 3, 2024, this document was served on DG-ILD@goodwinlaw.com, UTCvLiquidia-Del-23cv975@mwe.com and the persons listed below in the manner indicated:

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# EXHIBIT 4

Page 1

1 IN THE UNITED STATES DISTRICT COURT  
2 FOR THE DISTRICT OF DELAWARE

3 UNITED THERAPEUTICS Case No.  
4 CORPORATION, 23-975-RGA-SRF  
5 Plaintiff,  
6 vs.  
7 LIQUIDIA TECHNOLOGIES, INC.,  
8 Defendant.

10 \*\*\* [REDACTED] \*\*\*

11 VIDEOTAPED DEPOSITION  
12 OF  
13 PETER SMITH, Individually and as  
14 30(b)(6) Corporate Representative of  
15 UNITED THERAPEUTICS CORPORATION  
16 (Taken by Defendants)  
17 Raleigh, North Carolina  
18 Wednesday, November 13, 2024

19  
20  
21  
22  
23 Reported by Andrea L. Kingsley, RPR  
24  
25

<p style="text-align: right;">Page 46</p> <p>1           MR. SUKDUANG: And you can lodge 2       your objection. 3       Q. My question to you is do you know 4 personally whether as an inventor you owe a duty of 5 disclosure to the United States Patent and Trademark 6 Office? 7           MR. ROMEO: I will instruct you, to 8 the extent that answering that question 9 requires you -- to the extent that requires 10 you to divulge communications with counsel, I 11 would instruct you not to answer. But if you 12 can answer otherwise, go ahead. 13       A. I don't know. 14       Q. [REDACTED] 15 [REDACTED] 16 [REDACTED] 17 [REDACTED] 18       A. [REDACTED] 19       Q. Do you know why you're a named inventor 20 on the '327 patent? 21       A. Yes. 22           MR. ROMEO: Can I just jump in? 23           Again, I want to caution you not to 24 reveal the contents of any communications that 25 you've had with counsel. If you have an</p>	<p style="text-align: right;">Page 48</p> <p>1 [REDACTED] 2 [REDACTED] 3 [REDACTED] 4 [REDACTED] 5       Q. [REDACTED] 6 [REDACTED] 7 [REDACTED] 8           MR. ROMEO: Object to form. 9       A. [REDACTED] 10 [REDACTED] 11 [REDACTED] 12 [REDACTED] 13 [REDACTED] 14 [REDACTED] 15 [REDACTED] 16 [REDACTED] 17 [REDACTED] 18       Q. You understand, when you say "broad 19 Group 3," PH-ILD falls within the WHO Group 3 20 classification? 21           MR. ROMEO: Object to form. 22       A. Group 3 pulmonary hypertension includes 23 a number of different sets of etiologies. 24       Q. One of which is PH-ILD? 25       A. Yes.</p>
<p style="text-align: right;">Page 47</p> <p>1 understanding outside of those discussions, 2 you can answer. 3       A. I myself, Leigh Peterson and CQ were 4 responsible for conducting, reporting out, 5 unblinding, the data. 6       Q. "The data" is the INCREASE study; 7 correct? 8       A. The INCREASE study. 9       Q. And that is your understanding as to why 10 you're an inventor on the patent; correct? 11       A. Um-hmm. 12       Q. Can you go to -- remember I mentioned 13 numbers at the top of the patent? 14       A. Um-hmm. 15       Q. Can you go to column 54. 16           Do you see a section titled "What is 17 Claimed is," and there's numbers 1 through 19? 18       A. Yes. 19       Q. I'm asking you this question in terms of 20 your understanding. Okay? But whose idea was it to 21 test Tyvaso to improve exercise capacity in patients 22 with PH-ILD? 23           MR. ROMEO: Object to form. 24       A. [REDACTED] 25 [REDACTED]</p>	<p style="text-align: right;">Page 49</p> <p>1       Q. This retrospective study, chart study, 2 do you recall was that a paper by a Faria-Urbina and 3 Dr. Waxman? 4       A. Yes. 5       Q. Did it also include an abstract by a 6 Dr. Agarwal and Dr. Waxman? 7       A. I believe so. 8       Q. [REDACTED] 9 [REDACTED] 10 [REDACTED] 11 [REDACTED] 12 [REDACTED] 13 [REDACTED] 14       A. [REDACTED] 15 [REDACTED] 16 [REDACTED] 17       Q. We'll get to those papers later today. 18           You had mentioned your involvement in 19 the patent as conducting the INCREASE study, 20 reporting the data. I want to ask about your 21 knowledge regarding Leigh Peterson. 22           Was her involvement in the '327 patent 23 coextensive with what you identified or different? 24       A. I am not sure what you mean by 25 "coextensive."</p>

<p style="text-align: right;">Page 86</p> <p>1 researcher regarding the use of Tyvaso in PH-ILD?</p> <p>2 A. No.</p> <p>3 Q. To prepare for your testimony today did</p> <p>4 you speak to any of the clinicians associated with</p> <p>5 the INCREASE trial to prepare --</p> <p>6 A. No.</p> <p>7 Q. -- to prepare for your deposition today?</p> <p>8 A. No.</p> <p>9 Q. Would you consider, [REDACTED]</p> <p>10 [REDACTED] the individual clinicians in</p> <p>11 INCREASE to be researchers associated with the</p> <p>12 development of Tyvaso for the treatment of PH-ILD?</p> <p>13 MR. ROMEO: Object to form.</p> <p>14 A. Are you talking about the participating</p> <p>15 investigators?</p> <p>16 Q. Correct.</p> <p>17 A. And your question about the</p> <p>18 participating investigators --</p> <p>19 Q. Would you consider them to be</p> <p>20 researchers regarding the development and use of</p> <p>21 Tyvaso for the treatment of PH-ILD?</p> <p>22 MR. ROMEO: Object to form.</p> <p>23 A. They were collaborators on the research.</p> <p>24 Q. So you would consider them to be</p> <p>25 consultants, experts or clinicians associated</p>	<p style="text-align: right;">Page 88</p> <p>1 individuals, is that correct?</p> <p>2 A. Yes.</p> <p>3 Q. You spoke to none of the clinicians</p> <p>4 associated with the INCREASE study for the</p> <p>5 preparation of your deposition today?</p> <p>6 A. I didn't speak to any of the</p> <p>7 participating investigators that you mentioned.</p> <p>8 Nor did I speak to any of the steering committee</p> <p>9 members.</p> <p>10 Q. Other than [REDACTED], to</p> <p>11 your recollection who were the other steering</p> <p>12 committee members for INCREASE?</p> <p>13 A. Those were the [REDACTED] steering committee</p> <p>14 members.</p> <p>15 Q. Only those [REDACTED]?</p> <p>16 A. Only those [REDACTED].</p> <p>17 Q. Who else were part of the steering</p> <p>18 committee -- let me rephrase.</p> <p>19 Other than [REDACTED]</p> <p>20 who else was part of the steering committee for the</p> <p>21 INCREASE trial?</p> <p>22 A. Those are all the external members.</p> <p>23 Q. Who are the internal members?</p> <p>24 A. I don't know if that was formalized in a</p> <p>25 charter anywhere, so I can't say for sure.</p>
<p style="text-align: right;">Page 87</p> <p>1 with the development of Tyvaso for the treatment</p> <p>2 of PH-ILD?</p> <p>3 MR. ROMEO: Object to form.</p> <p>4 A. Not all of them, but some of them were</p> <p>5 collaborators.</p> <p>6 Q. What is the difference between, in your</p> <p>7 mind, a collaborator --</p> <p>8 A. You had a number of adjectives in there.</p> <p>9 So that's why I wanted to make sure that was clear.</p> <p>10 Q. Would they be considered clinicians --</p> <p>11 A. Yes.</p> <p>12 Q. I'm sorry. Let's make sure we don't</p> <p>13 speak over each other. Okay?</p> <p>14 Would those individuals -- would the</p> <p>15 clinicians that participated in the INCREASE trial,</p> <p>16 would you consider them to be clinicians associated</p> <p>17 with the development and use of Tyvaso for the</p> <p>18 treatment of PH-ILD?</p> <p>19 MR. ROMEO: Object to form.</p> <p>20 A. Yes.</p> <p>21 Q. Other than [REDACTED]</p> <p>22 how many other clinicians were site investigators</p> <p>23 for INCREASE?</p> <p>24 A. I don't.</p> <p>25 Q. It was more than those three</p>	<p style="text-align: right;">Page 89</p> <p>1 Q. Other than formalizing in a charter, who</p> <p>2 participated in steering committee meetings</p> <p>3 internally for UTC?</p> <p>4 A. [REDACTED]</p> <p>5 [REDACTED]</p> <p>6 Those were the primary participants. We</p> <p>7 may have an ad hoc member here or there attend, but</p> <p>8 those were the primary participants.</p> <p>9 Q. What was the external members of the</p> <p>10 steering committee's responsibilities associated</p> <p>11 with their participation in the INCREASE trial?</p> <p>12 For purposes of my question, I'm talking</p> <p>13 about the external steering committee members.</p> <p>14 A. Yeah, a study steering committee</p> <p>15 member -- steering committees generally provide</p> <p>16 input on design of the study, they provide input on</p> <p>17 the ongoing conduct of the study, and then they're</p> <p>18 involved as well with the reporting of the results</p> <p>19 at the end of the study.</p> <p>20 Q. With respect to design, what would that</p> <p>21 include? "Design of the study" you mentioned. What</p> <p>22 would that include with respect to the steering</p> <p>23 committee members who were external?</p> <p>24 A. The clinical study protocol.</p> <p>25 Q. Would that include the dosing regimen?</p>

	Page 90		Page 92
1	A. They may contribute to that.	1	[REDACTED]
2	Q. Would that include the inclusion	2	A. [REDACTED]
3	criteria?	3	Q. [REDACTED]
4	A. Yes.	4	A. [REDACTED]
5	Q. Would that include the exclusion	5	Q. [REDACTED]
6	criteria?	6	A. [REDACTED]
7	A. Yes.	7	[REDACTED]
8	Q. Would that include the study duration?	8	Q. Around March of 2017 did you report to
9	A. Yes.	9	Leigh Peterson?
10	Q. Would that include whether the study	10	A. When she took over as the head of
11	would be blinded or unblinded?	11	product development I reported to Leigh Peterson.
12	A. Yes.	12	Q. Did you report to someone prior to Leigh
13	Q. Would that include whether the study	13	Peterson?
14	included placebo or no placebo?	14	A. Prior to that I reported to Kevin
15	A. Yeah. So those are all things that are	15	Laliberte.
16	included in clinical studies. Right? And when you	16	Q. Just for the record, who do you report
17	have external contributors, they all provide	17	to today?
18	different levels of contribution to study designs.	18	A. Leigh Peterson.
19	So any and all of those could have been	19	Q. Still Leigh Peterson?
20	participants.	20	A. Yes.
21	Whether one provided something or	21	Q. Are you still on the product development
22	another provided something, I mean, these are broad	22	team?
23	generalities that I think you're trying to make.	23	A. Yes.
24	That's what I'm trying to parse out here.	24	Q. Is she still head of the product
25	Q. Sure.	25	development team?
	Page 91		Page 93
1	[REDACTED]	1	A. Yes.
2	[REDACTED]	2	Q. [REDACTED]
3	[REDACTED]	3	[REDACTED]
4	A. [REDACTED]	4	A. [REDACTED]
5	Q. [REDACTED]	5	[REDACTED]
6	[REDACTED]	6	[REDACTED]
7	A. [REDACTED]	7	Q. Going back to the topics we identified
8	[REDACTED]	8	other than Topic 1, what did you do to prepare for
9	[REDACTED]	9	those topics?
10	Q. [REDACTED]	10	A. I'm sorry, say that again.
11	[REDACTED]	11	Q. Other than Topic 1, the topics you've
12	A. [REDACTED]	12	been identified as a corporate witness, what did you
13	Q. [REDACTED]	13	do to prepare?
14	[REDACTED]	14	A. I spoke to those four individuals that I
15	A. [REDACTED]	15	mentioned and also reviewed several documents.
16	Q. [REDACTED]	16	Q. What documents did you review?
17	[REDACTED]	17	A. Probably between 25 and 30 documents.
18	A. [REDACTED]	18	Q. What types of documents were those?
19	Q. [REDACTED]	19	A. So I reviewed -- with respect to which
20	[REDACTED]	20	topics are you talking about?
21	A. [REDACTED]	21	Q. The topics associated with the design,
22	[REDACTED]	22	development and conduct of the INCREASE trial.
23	Q. [REDACTED]	23	A. Got it. Right.
24	A. [REDACTED]	24	In that case, yes. So for the design,
25	Q. [REDACTED]	25	development and conduct, I don't know how many

<p style="text-align: right;">Page 118</p> <p>1 [REDACTED] 2 [REDACTED] 3 MR. ROMEO: Object to form. 4 A. [REDACTED] 5 Q. [REDACTED] 6 [REDACTED] 7 [REDACTED] 8 [REDACTED] 9 [REDACTED] 10 MR. ROMEO: Object to form. 11 A. [REDACTED] 12 [REDACTED] 13 [REDACTED] 14 [REDACTED] 15 [REDACTED] 16 [REDACTED] 17 [REDACTED] 18 Q. [REDACTED] 19 [REDACTED] 20 MR. ROMEO: Object to form. 21 A. [REDACTED] 22 [REDACTED] 23 [REDACTED] 24 Q. [REDACTED] 25 [REDACTED]</p>	<p style="text-align: right;">Page 120</p> <p>1 [REDACTED] 2 MR. ROMEO: Object to form. 3 A. I believe the conclusion of the paper 4 also indicates that as well. 5 Q. Dr. Waxman's paper? 6 A. Yes, the papers we've talked about. 7 That additional study is warranted. 8 Q. Did he have this idea before UTC had the 9 idea? 10 MR. ROMEO: Object to form. 11 A. I don't know. I can't say. I can't 12 speculate on that. 13 (Smith Exhibit 6, Slide deck, [REDACTED] 14 [REDACTED] 15 [REDACTED], Bates UTC_PH-ILD_082768 - 16 82791, marked for identification, as of this 17 date.) 18 BY MR. SUKDUANG: 19 Q. I'm marking as Smith Exhibit 6 a 20 document titled [REDACTED] 21 [REDACTED], bearing production 22 number UTC_PH-ILD_082768 through 82791. 23 Dr. Smith, have you ever seen this 24 document before? 25 A. I don't think so.</p>
<p style="text-align: right;">Page 119</p> <p>1 MR. ROMEO: Object to form. 2 A. [REDACTED] 3 Q. [REDACTED] 4 [REDACTED] 5 MR. ROMEO: Object to form. 6 A. [REDACTED] 7 Q. [REDACTED] 8 [REDACTED] 9 [REDACTED] 10 MR. ROMEO: Object to form. 11 A. [REDACTED] 12 [REDACTED] 13 [REDACTED] 14 [REDACTED] 15 [REDACTED] 16 [REDACTED] 17 [REDACTED] 18 Q. [REDACTED] 19 [REDACTED] 20 MR. ROMEO: Object to form. 21 A. [REDACTED] 22 [REDACTED] 23 [REDACTED] 24 Q. [REDACTED] 25 [REDACTED]</p>	<p style="text-align: right;">Page 121</p> <p>1 Q. So you don't know who prepared it? 2 A. Pardon? 3 Q. You do not know who prepared it? 4 A. I don't. 5 Q. If you turn to the slide -- [REDACTED] 6 [REDACTED] 7 A. [REDACTED] 8 Q. [REDACTED] 9 [REDACTED] 10 A. [REDACTED] 11 Q. [REDACTED] 12 MR. ROMEO: Object to form. 13 Q. Let me ask you a better question. 14 [REDACTED] 15 [REDACTED] 16 [REDACTED] 17 MR. ROMEO: Object to form. 18 A. [REDACTED] 19 Q. Can you turn to the page ending in 772. 20 [REDACTED] 21 [REDACTED] 22 A. [REDACTED] 23 Q. [REDACTED] 24 [REDACTED] 25 A. [REDACTED]</p>

<p style="text-align: right;">Page 126</p> <p>1 MR. ROMEO: Object to form. 2 A. [REDACTED] 3 [REDACTED] 4 [REDACTED] 5 [REDACTED] 6 [REDACTED] 7 Q. [REDACTED] 8 [REDACTED] 9 MR. ROMEO: Object to form. 10 A. [REDACTED] 11 Q. I want to talk about your use of the 12 word "hypothesis." 13 When you're talking about a hypothesis, 14 are you looking at that as we need more data to get 15 an FDA-approved label? 16 MR. ROMEO: Object to form. 17 A. Well, in drug development that's 18 generally -- I'm sure you know this. How it works 19 is we start with a hypothesis, and it's not until 20 we've performed a well-controlled clinical trial 21 that -- and regulatory agencies agree with that, 22 that we've essentially proved it. 23 There's always hypothesis-generating 24 material. 25 Q. What do you mean, "proved it"?</p>	<p style="text-align: right;">Page 128</p> <p>1 Q. Yes. 2 A. Yes. 3 Q. So despite the well-controlled trial 4 proving for FDA purposes, clinicians were still 5 using Tyvaso to treat this patient population prior 6 to that? 7 MR. ROMEO: Object to form. 8 A. I'm sure you've heard this from others 9 as well, but there were a large number of different 10 therapies that were tried in this patient 11 population that failed due to safety or efficacy. 12 So the predominance of this was not a readily 13 accepted medical treatment by any means. If 14 anything, there was a lot of doubt, a lot of 15 concern around finding a treatment that is safe and 16 effective in this patient population because of all 17 those previous studies. So any off-label usage 18 would have been, as I mentioned, infrequent. 19 Q. [REDACTED] 20 [REDACTED] 21 [REDACTED] 22 [REDACTED] 23 [REDACTED] 24 MR. ROMEO: Object to form. 25 A. [REDACTED]</p>
<p style="text-align: right;">Page 127</p> <p>1 A. Meaning we met our outcome. 2 Q. And in terms of proving it, you're 3 talking about you have a hypothesis and then you do 4 a clinical trial to prove sufficient to get 5 regulatory approval? 6 MR. ROMEO: Object to form. 7 A. Well, if this is in regards to the 8 INCREASE study and the INCREASE study demonstrating 9 a definitive endpoint being met and then that 10 ultimately was accepted by the FDA, then yes. 11 Q. When you're talking about "hypothesis" 12 in the context of your testimony today, is that what 13 you're referring to? 14 MR. ROMEO: Object to form. 15 A. Hypotheses that led to a well-controlled 16 clinical trial? Yes. 17 Q. You understand that UTC had knowledge of 18 doctors -- this goes to Topic 1 -- of doctors 19 actually prescribing Tyvaso for PH-ILD patients; 20 correct? 21 A. So what I mentioned previously is that 22 there was the case report. There was the Parikh 23 article. There was the Waxman data. 24 And so if that is what you're referring 25 to?</p>	<p style="text-align: right;">Page 129</p> <p>1 Q. Are you aware of any study, any paper, 2 where inhaled treprostinil was used in PH-ILD and 3 failed? 4 MR. ROMEO: Object to form. 5 A. Inhaled treprostinil used in PH-ILD and 6 failed? I'm not recalling. Yeah. 7 Q. You can put this slide deck aside. 8 (Smith Exhibit 7, Document titled 9 [REDACTED] 10 [REDACTED] 11 [REDACTED] 12 [REDACTED] 13 [REDACTED] 14 [REDACTED] 15 marked for identification, as of this date.) 16 BY MR. SUKDUANG: 17 Q. Dr. Smith, I'm marking as Exhibit 7 a 18 document titled [REDACTED] 19 [REDACTED] 20 [REDACTED] 21 [REDACTED] 22 [REDACTED] 23 bearing production numbers UTC_PH-ILD_054882 through 24 054950. 25 [REDACTED]</p>

	Page 130		Page 132
1	[REDACTED]	1	A. They're a physician. And they can have
2	A. [REDACTED]	2	a variety of roles. They can contribute to the
3	Q. [REDACTED]	3	scientific -- contribute to the protocol. They
4	A. [REDACTED]	4	monitor safety primarily during this study in terms
5	Q. [REDACTED]	5	of, you know, safety data that may come up. They
6	[REDACTED]	6	might respond to questions from investigators.
7	A. [REDACTED]	7	That's generally what a medical monitor would do.
8	Q. [REDACTED]	8	Q. In preparing for your topics today, did
9	[REDACTED]	9	you discuss with anyone who was involved in
10	A. [REDACTED]	10	preparing this protocol?
11	Q. [REDACTED]	11	A. Yes.
12	[REDACTED]	12	Q. Who was involved in preparing this
13	A. [REDACTED]	13	protocol?
14	Q. [REDACTED]	14	A. [REDACTED]
15	[REDACTED]	15	[REDACTED]
16	A. [REDACTED]	16	[REDACTED]
17	[REDACTED]	17	[REDACTED]
18	Q. I know. I'm going to ask you specific	18	Q. [REDACTED]
19	questions though, just for my record. Okay?	19	[REDACTED]
20	A. (Indicating.)	20	[REDACTED]
21	Q. [REDACTED]	21	A. [REDACTED]
22	[REDACTED]	22	Q. [REDACTED]
23	A. [REDACTED]	23	[REDACTED]
24	Q. [REDACTED]	24	[REDACTED]
25	[REDACTED]	25	A. [REDACTED]
	Page 131		Page 133
1	A. [REDACTED]	1	Q. [REDACTED]
2	Q. [REDACTED]	2	[REDACTED]
3	[REDACTED]	3	[REDACTED]
4	[REDACTED]	4	A. [REDACTED]
5	A. [REDACTED]	5	Q. [REDACTED]
6	Q. [REDACTED]	6	[REDACTED]
7	[REDACTED]	7	[REDACTED]
8	[REDACTED]	8	[REDACTED]
9	A. [REDACTED]	9	[REDACTED]
10	Q. [REDACTED]	10	[REDACTED]
11	[REDACTED]	11	MR. ROMEO: Object to form.
12	A. [REDACTED]	12	A. [REDACTED]
13	[REDACTED]	13	[REDACTED]
14	Q. [REDACTED]	14	Q. [REDACTED]
15	[REDACTED]	15	[REDACTED]
16	[REDACTED]	16	[REDACTED]
17	A. [REDACTED]	17	A. [REDACTED]
18	Q. [REDACTED]	18	Q. [REDACTED]
19	[REDACTED]	19	[REDACTED]
20	A. [REDACTED]	20	A. [REDACTED]
21	Q. [REDACTED]	21	[REDACTED]
22	A. [REDACTED]	22	Q. [REDACTED]
23	Q. [REDACTED]	23	[REDACTED]
24	A. [REDACTED]	24	[REDACTED]
25	Q. What is a medical monitor?	25	[REDACTED]

1 A. Yeah, I didn't join the company until 2 November 2016, correct. 3 Q. [REDACTED] 4 [REDACTED] 5 [REDACTED] 6 [REDACTED] 7 [REDACTED] 8 MR. ROMEO: Object to form of the 9 question. 10 A. [REDACTED] 11 [REDACTED] 12 [REDACTED] 13 I joined the company in November 2016, 14 and then [REDACTED] 15 [REDACTED] 16 Q. [REDACTED] 17 A. [REDACTED] 18 Q. [REDACTED] 19 [REDACTED] 20 [REDACTED] 21 [REDACTED] 22 [REDACTED] 23 MR. ROMEO: Object to form. 24 A. [REDACTED] 25 Q. [REDACTED]	Page 150	1 A. [REDACTED] 2 [REDACTED]. 3 Q. In terms of reporting out the study 4 in The New England Journal of Medicine, the 5 steering committee members were also authors of 6 those papers? 7 A. Yes. 8 (Smith Exhibit 13, Document 9 entitled [REDACTED] 10 [REDACTED] 11 Bates UTC_PH-ILD_077582 - 620, marked for 12 identification, as of this date.) 13 BY MR. SUKDUANG: 14 Q. Dr. Smith, I'm handing you Smith Exhibit 15 13, a document entitled [REDACTED] 16 [REDACTED] 17 [REDACTED] It bears production numbers 18 UTC_PH-ILD_077582 through 077620. 19 [REDACTED] 20 [REDACTED] 21 A. [REDACTED] 22 Q. It's dated [REDACTED]. It says it's 23 [REDACTED] 24 [REDACTED] 25 Do you see that?	Page 152
1 [REDACTED] 2 [REDACTED] 3 A. [REDACTED] 4 [REDACTED] 5 [REDACTED] 6 [REDACTED] 7 [REDACTED] 8 [REDACTED]. 9 Q. [REDACTED] 10 [REDACTED] 11 [REDACTED] 12 MR. ROMEO: Object to form. 13 A. [REDACTED] 14 [REDACTED] 15 [REDACTED] 16 [REDACTED] 17 [REDACTED] 18 [REDACTED] 19 Aaron Waxman was specifically an 20 investigator, as was Steve Nathan. They were both 21 participating study investigators. Vic Tapson was 22 not. 23 Q. [REDACTED] 24 [REDACTED] 25 [REDACTED]	Page 151	1 A. Um-hmm. 2 Q. [REDACTED] 3 [REDACTED] 4 [REDACTED] 5 A. [REDACTED] 6 Q. [REDACTED] 7 MR. ROMEO: Object to form. 8 A. [REDACTED] 9 [REDACTED] 10 Q. [REDACTED] 11 [REDACTED] 12 [REDACTED] 13 A. [REDACTED] 14 Q. What is an onsite site evaluation visit? 15 A. So prior to agreeing that a clinical 16 trial site will be able to participate in a 17 clinical trial, there's a site evaluation visit 18 that's done. And it's just like it says, it's 19 basically to evaluate that a site is capable of -- 20 an investigator site is capable of conducting the 21 clinical trial protocol that you're planning on 22 conducting. 23 Q. So each site that agreed to participate 24 in the INCREASE study had to have a site visit by 25 UTC to confirm, okay, you guys can participate?	Page 153

<p style="text-align: right;">Page 230</p> <p>1 breaths, but you'd agree that both the maintenance 2 dosage in 2009 and 2021 allow you to go to a target 3 dose of 9 breaths?</p> <p>4 A. So, yes, in the 2009 version the target 5 dose was 9 breaths, and in the 2021 version the 6 target dose was 9 to 12 breaths per treatment 7 session.</p> <p>8 Q. So the 2009 label overlaps with the 2021 9 label with respect to maintenance dosage of Tyvaso?</p> <p>10 MR. ROMEO: Object to form.</p> <p>11 A. There was additional color around the 12 dose range based upon prior clinical trial 13 information that was put into the 2021 label 14 maintenance dosing section.</p> <p>15 Q. Correct. But in the 2021 label and the 16 2009 label for Tyvaso maintenance dosage overlaps?</p> <p>17 A. Yes, they both have nine breaths as a 18 potential target.</p> <p>19 Q. So as of 2009, if I gave Tyvaso in 20 accordance with the label instructions on dosage to 21 a patient with PH-ILD, I would have treated the 22 patient's PH-ILD?</p> <p>23 MR. ROMEO: Object to form.</p> <p>24 A. Well, in -- you said if you did this in 25 2009 or if you did this today?</p>	<p style="text-align: right;">Page 232</p> <p>1 Q. Let me give you my full question. 2 I'm in 2009. Put yourself there. 3 A. I'm there. 4 Q. You haven't graduated to 2021 yet. 5 A. Okay. 6 Q. I'm a doctor, and I give Tyvaso in 7 accordance with the 2009 label to a PH-ILD patient, 8 I'm going to safely and effectively treat their 9 PH-ILD; correct?</p> <p>10 MR. ROMEO: Object to form.</p> <p>11 A. I feel like this is Back to the Future. 12 I'm losing the string here, because it seems like 13 an odd turn of phrase that you're trying to ask me 14 a question on. 15 If you are assuming that in 2009 we had 16 the results of the INCREASE study -- 17 Q. No. I'm excluding that. You have not 18 graduated to 2021 -- 19 A. I can't speculate. 20 Q. Why not? 21 A. Because I wouldn't have had the results 22 of the INCREASE study in 2009. 23 Q. Is it also because you're not a medical 24 doctor treating PAH patients or PH-ILD patients? 25 MR. ROMEO: Object to form.</p>
<p style="text-align: right;">Page 231</p> <p>1 Q. If I did this in 2009 -- 2 A. Well, in 2009 we wouldn't have had that 3 information, so it's hard to speculate. 4 Q. Today you have that information. 5 A. Today we have that information, and we 6 know that today the doses of -- target dose of 7 9 breaths that was used in the INCREASE study for a 8 patient dose today based upon the results of the 9 INCREASE study had demonstrated efficacy -- or 10 demonstrated hitting the primary endpoint. 11 Q. So if I went back in 2009 and applied 12 the same dosing from the Tyvaso 2009 label to a 13 PH-ILD patient, I could safely and effectively treat 14 their PH-ILD?</p> <p>15 MR. ROMEO: Object to form.</p> <p>16 A. I'm not sure I understand the question. 17 Q. If I was a doctor in 2009 and I had a 18 PH-ILD patient and I gave them Tyvaso in accordance 19 with the 2009 label -- 20 A. And we already had the results from the 21 INCREASE study retrospectively. 22 Q. No. In 2009 -- 23 A. I don't know -- to me it seems like 24 you're parsing out the dates intentionally, and I'm 25 not understanding why.</p>	<p style="text-align: right;">Page 233</p> <p>1 A. That's also a contributing factor. 2 Q. So the INCREASE study in your mind 3 confirmed that if I use Tyvaso according to the 4 dosing regimen in 2009, I could treat a PH-ILD 5 patient?</p> <p>6 MR. ROMEO: Object to form.</p> <p>7 A. The INCREASE study, which used 9 as the 8 target dose, up to 12, confirmed that Tyvaso was 9 safe and effective in treating patients with 10 PH-ILD.</p> <p>11 MR. SUKDUANG: I've got no further 12 questions right now, Dr. Smith. Your counsel 13 probably has some questions for you, but I 14 appreciate your time.</p> <p>15 THE WITNESS: Thank you.</p> <p>16 EXAMINATION BY</p> <p>17 MR. ROMEO:</p> <p>18 Q. Dr. Smith, I do have a couple questions 19 for you. 20 Could you pull out Exhibit 7 from your 21 pile. I'm going to ask you about 7 and 12. 22 MR. SUKDUANG: Can you let me know 23 what 7 is? 24 MR. ROMEO: 7 is [REDACTED]</p>

1 [REDACTED] 2 BY MR. ROMEO: 3 Q. Dr. Smith, let's start with Exhibit 7, 4 please. 5 Do you recognize this as the 6 [REDACTED] 7 [REDACTED] 8 A. [REDACTED] 9 Q. And do you recall counsel asking you 10 questions about this document? 11 A. Yes. 12 Q. If you turn to the second page, where 13 [REDACTED] 14 A. [REDACTED]. 15 Q. [REDACTED] 16 [REDACTED] 17 [REDACTED] 18 A. [REDACTED] 19 Q. [REDACTED] 20 [REDACTED] 21 A. [REDACTED] 22 Q. [REDACTED] 23 [REDACTED] 24 [REDACTED] 25 [REDACTED]	Page 234  1 [REDACTED] 2 [REDACTED] 3 [REDACTED] 4 [REDACTED] 5 [REDACTED] 6 [REDACTED] 7 [REDACTED] 8 [REDACTED] 9 [REDACTED] 10 [REDACTED] 11 [REDACTED] 12 [REDACTED] 13 [REDACTED] 14 Q. Thank you. 15 [REDACTED] 16 [REDACTED] 17 [REDACTED] 18 A. [REDACTED] 19 Q. [REDACTED] 20 [REDACTED] 21 [REDACTED] 22 [REDACTED] 23 [REDACTED] 24 MR. SUKDUANG: Objection. Calls 25 for a legal conclusion and expert testimony.
1 A. [REDACTED] 2 Q. [REDACTED] 3 [REDACTED] 4 A. [REDACTED] 5 Q. [REDACTED] 6 [REDACTED] 7 A. [REDACTED] 8 [REDACTED] 9 [REDACTED] 10 Q. You can put those aside. 11 Do you recall counsel earlier today 12 asking you about the origins of the INCREASE study 13 and where it started? 14 A. Yes. 15 Q. [REDACTED] 16 [REDACTED] 17 [REDACTED] 18 [REDACTED] 19 A. [REDACTED] 20 Q. [REDACTED] 21 [REDACTED] 22 [REDACTED] 23 [REDACTED] 24 A. [REDACTED] 25 [REDACTED]	Page 235  1 The witness testified earlier today that he's 2 not a lawyer, and [REDACTED] 3 [REDACTED] is legal terminology. 4 But you can go ahead and answer. 5 And vague. 6 A. [REDACTED] 7 [REDACTED] 8 [REDACTED] 9 Q. So let me ask the question without the 10 legal language that he objected to. 11 [REDACTED] 12 [REDACTED] 13 [REDACTED] 14 [REDACTED] 15 A. [REDACTED] 16 Q. [REDACTED] 17 [REDACTED] 18 A. [REDACTED] 19 Q. Do you recall earlier today counsel 20 asking you questions about whose idea it was to 21 begin the INCREASE study? 22 A. Yes. 23 Q. [REDACTED] 24 [REDACTED] 25 [REDACTED]

1 A. [REDACTED] 2 Q. [REDACTED] 3 [REDACTED] 4 [REDACTED] 5 [REDACTED] 6 MR. SUKDUANG: Objection. Vague. 7 Calls for a legal conclusion. 8 A. Sorry, ask the question again. 9 Q. Let me start again. 10 [REDACTED] 11 [REDACTED] 12 A. [REDACTED] 13 Q. [REDACTED] 14 A. [REDACTED] 15 Q. [REDACTED] 16 [REDACTED] 17 [REDACTED] 18 MR. SUKDUANG: Objection. Vague. 19 And lack of foundation. The witness was not 20 there in [REDACTED] 21 A. [REDACTED] 22 [REDACTED] 23 [REDACTED] 24 [REDACTED] at 25 [REDACTED]	Page 238	1 Q. Can you explain that a little bit? 2 A. [REDACTED] 3 [REDACTED] 4 [REDACTED] 5 [REDACTED] 6 [REDACTED] 7 [REDACTED] 8 [REDACTED] 9 [REDACTED] 10 [REDACTED] 11 MR. ROMEO: I have nothing further at this time. 13 FURTHER EXAMINATION 14 BY MR. SUKDUANG: 15 Q. Did counsel put in front of you any 16 documents to prepare for your deposition today that 17 said, [REDACTED] 18 [REDACTED] 19 A. Did they put a document in front of me? 20 Q. Yes, written down, that [REDACTED] 21 [REDACTED] 22 [REDACTED] 23 [REDACTED] 24 MR. ROMEO: Object to form. 25 A. [REDACTED]	Page 240
1 [REDACTED] 2 Q. Why was it important for UTC to perform 3 a well-controlled registration study? 4 A. That's an FDA requirement. You have to 5 have a well-controlled registration study in order 6 to gain approval and provide some definitive 7 answers or definitive conclusions about a clinical 8 trial. 9 Q. Was the Waxman data placebo-controlled? 10 A. No. 11 Q. [REDACTED] 12 [REDACTED] 13 MR. SUKDUANG: Objection. Lack of foundation. The witness was not involved in 15 [REDACTED]. 16 A. [REDACTED] 17 [REDACTED] 18 [REDACTED] 19 [REDACTED] 20 [REDACTED] 21 [REDACTED] 22 [REDACTED] 23 Q. [REDACTED] 24 [REDACTED] 25 A. [REDACTED]	Page 239	1 Q. [REDACTED] 2 [REDACTED] 3 [REDACTED] 4 A. [REDACTED] 5 [REDACTED] 6 [REDACTED] 7 [REDACTED] 8 [REDACTED] 9 Q. [REDACTED] 10 [REDACTED] 11 MR. ROMEO: Object to form. 12 A. [REDACTED] 13 [REDACTED]. 14 Q. [REDACTED] 15 [REDACTED] 16 [REDACTED] 17 MR. ROMEO: Object to form. 18 A. [REDACTED] 19 [REDACTED] 20 [REDACTED] 21 [REDACTED] 22 [REDACTED] 23 Q. [REDACTED] 24 A. [REDACTED]. 25 Q. [REDACTED]	Page 241

		Page 242	Page 244
1	A.	[REDACTED]	[REDACTED]
2	Q.	[REDACTED]	[REDACTED]
3	A.	[REDACTED]	[REDACTED]
4	Q.	[REDACTED]	[REDACTED]
5	A.	[REDACTED]	[REDACTED]
6	Q.	[REDACTED]	[REDACTED]
7	A.	[REDACTED]	[REDACTED]
8		[REDACTED]	[REDACTED]
9		[REDACTED]	[REDACTED]
10		[REDACTED]	[REDACTED]
11		[REDACTED]	[REDACTED]
12	Q.	[REDACTED]	[REDACTED]
13		[REDACTED]	[REDACTED]
14	A.	[REDACTED]	[REDACTED]
15	Q.	[REDACTED]	[REDACTED]
16		[REDACTED]	[REDACTED]
17	A.	[REDACTED]	[REDACTED]
18		[REDACTED]	[REDACTED]
19		[REDACTED]	[REDACTED]
20		[REDACTED]	[REDACTED]
21		[REDACTED]	[REDACTED]
22		[REDACTED]	[REDACTED]
23	Q.	So clinical trials, Phase 3 clinical	
24		trials, do fail; correct?	MR. ROMEO: Object to form.
25			MR. ROMEO: Object to form.
		Page 243	Page 245
1	A.	Yes. Clinical trials do fail, yes.	[REDACTED]
2	Q.	[REDACTED]	[REDACTED]
3		[REDACTED]	[REDACTED]
4		[REDACTED]	[REDACTED]
5		[REDACTED]	[REDACTED]
6		[REDACTED]	[REDACTED]
7		[REDACTED]	[REDACTED]
8		MR. ROMEO: Object to form.	
9	A.	[REDACTED]	[REDACTED]
10		[REDACTED]	[REDACTED]
11		[REDACTED]	[REDACTED]
12		[REDACTED]	[REDACTED]
13		[REDACTED]	[REDACTED]
14		[REDACTED]	[REDACTED]
15	Q.	[REDACTED]	[REDACTED]
16		[REDACTED]	[REDACTED]
17		[REDACTED]	[REDACTED]
18		[REDACTED]	[REDACTED]
19		[REDACTED]	[REDACTED]
20	A.	[REDACTED]	[REDACTED]
21	Q.	[REDACTED]	[REDACTED]
22		MR. ROMEO: Object to form.	
23	A.	[REDACTED]	[REDACTED]
24		[REDACTED]	[REDACTED]
25		[REDACTED]	[REDACTED]

62 (Pages 242 - 245)

<p style="text-align: right;">Page 246</p> <p>1 STATE OF NORTH CAROLINA      2 WAKE COUNTY      3 REPORTER'S CERTIFICATE      4 I, Andrea L. Kingsley, a Notary Public      5 in and for the State of North Carolina, do hereby      6 certify that there came before me on Wednesday,      7 November 17, 2024, the person hereinbefore named,      8 who was by me duly sworn to testify to the truth      9 and nothing but the truth of his knowledge      10 concerning the matters in controversy in this      11 cause; that the witness was thereupon examined      12 under oath, the examination reduced to typewriting      13 under my direction, and the deposition is a true      14 record of the testimony given by the witness.      15 I further certify that I am neither      16 attorney or counsel for, nor related to or employed      17 by, any attorney or counsel employed by the parties      18 hereto or financially interested in the action.</p> <p>19 IN WITNESS WHEREOF, I have hereto set      20 my <span style="margin-left: 100px;">ovember, 2024.</span>      21       22      23 Andrea L. Kingsley, Notary Public      24 Notary Public #201903800023      25</p>	<p style="text-align: right;">Page 248</p> <p>1 United Therapeutics Corporation v. Liquidia Technologies, Inc.      2 Peter Smith - 30(b)(6) UTC (#6983054)      3 E R R A T A S H E E T      4 PAGE ____ LINE ____ CHANGE _____      5 _____      6 REASON _____      7 PAGE ____ LINE ____ CHANGE _____      8 _____      9 REASON _____      10 PAGE ____ LINE ____ CHANGE _____      11 _____      12 REASON _____      13 PAGE ____ LINE ____ CHANGE _____      14 _____      15 REASON _____      16 PAGE ____ LINE ____ CHANGE _____      17 _____      18 REASON _____      19 PAGE ____ LINE ____ CHANGE _____      20 _____      21 REASON _____      22 _____      23 _____      24 Peter Smith - 30(b)(6) UTC Date      25</p>
<p style="text-align: right;">Page 247</p> <p>1 Eric T. Romeo, Esq.      2 eromeo@goodwinlaw.com      3 November 18, 2024      4 RE: United Therapeutics Corporation v. Liquidia Technologies      5 11/13/2024, Peter Smith - 30(b)(6) UTC (#6983054)      6 The above-referenced transcript is available for      7 review.      8 Within the applicable timeframe, the witness should      9 read the testimony to verify its accuracy. If there are      10 any changes, the witness should note those with the      11 reason, on the attached Errata Sheet.      12 The witness should sign the Acknowledgment of      13 Deponent and Errata and return to the deposing attorney.      14 Copies should be sent to all counsel, and to Veritext at      15 cs-midatlantic@veritext.com.      16 Return completed errata within 30 days from      17 receipt of testimony.      18 If the witness fails to do so within the time      19 allotted, the transcript may be used as if signed.      20      21      22 Yours,      23 Veritext Legal Solutions      24      25</p>	<p style="text-align: right;">Page 249</p> <p>1 United Therapeutics Corporation v. Liquidia Technologies, Inc.      2 Peter Smith - 30(b)(6) UTC (#6983054)      3 ACKNOWLEDGEMENT OF DEPONENT      4 I, Peter Smith - 30(b)(6) UTC, do hereby declare that I      5 have read the foregoing transcript, I have made any      6 corrections, additions, or changes I deemed necessary as      7 noted above to be appended hereto, and that the same is      8 a true, correct and complete transcript of the testimony      9 given by me.      10      11 _____      12 Peter Smith - 30(b)(6) UTC Date      13 *If notary is required      14 SUBSCRIBED AND SWORN TO BEFORE ME THIS      15 _____ DAY OF _____, 20____.      16      17      18 _____      19 NOTARY PUBLIC      20      21      22      23      24      25</p>

# EXHIBIT 5

[REDACTED]

Page 1

1 VOLUME: I  
2 EXHIBITS: 1 to 22  
3

4 UNITED STATES DISTRICT COURT  
5 FOR THE DISTRICT OF DELAWARE

6 Civil Action No. 1:23-CV-00975-RGA

7 UNITED THERAPEUTICS )  
8 CORPORATION, )  
9 Plaintiff, )  
10 vs. )  
11 LIQUIDIA TECHNOLOGIES, )  
12 INC., )  
13 Defendant. )

14 VIDEOTAPED DEPOSITION OF AARON B.  
15 WAXMAN, M.D., called as a witness on behalf  
16 of the Defendant, pursuant to the applicable  
17 provisions of the Federal Rules of Civil  
18 Procedure, before Jeanette N. Maracas,  
19 Registered Professional Reporter and Notary  
20 Public in and for the Commonwealth of  
21 Massachusetts, at the Offices of Goodwin  
22 Procter, LLP, 100 Northern Avenue, Boston,  
23 Massachusetts, on Thursday, December 12,  
24 2024, commencing at 9:05 a.m.

<p style="text-align: right;">Page 42</p> <p>1       vasodilate in the areas where the inhaled 2       treprostinil is actually delivered, is 3       that right?</p> <p>4            MR. JACKSON: Objection, calls for 5            expert testimony.</p> <p>6   A. Yes.</p> <p>7   Q. And in this case, the area of delivery is 8       the lung, correct?</p> <p>9   A. What?</p> <p>10   Q. In the case of inhaled treprostinil, the 11      area of delivery is the lung?</p> <p>12   A. Yes.</p> <p>13   Q. What did you mean by "preserving V/Q"? 14      What does that mean?</p> <p>15            MR. JACKSON: Objection, form, calls 16      for expert testimony.</p> <p>17   A. Again, the thinking was that you don't want 18      to override what the lung is, has evolved 19      to do because you can have adverse effects 20      if you override what the lung does normally. 21      So by delivering a drug to those areas of 22      well-ventilated lung, it's more likely to 23      only dilate vessels that are perfusing those 24      areas of lung.</p> <p>25   Q. What did you mean by, when you wrote</p>	<p style="text-align: right;">Page 44</p> <p>1       but Manyoo Agarwal was an intrical part 2       of the study.</p> <p>3   Q. Other than yourself and Dr. Agarwal, were 4       there any other individuals in your group 5       that you recall taking part in this study?</p> <p>6   A. There were a number of individuals who take 7       part in all of the studies that I conduct.</p> <p>8   Q. Was Dr. Agarwal a practicing physician like 9       yourself?</p> <p>10   A. He was a post-graduate fellow. He was not 11      practicing, per se. He was there to do 12      research with me.</p> <p>13   Q. Were there any other physicians that treated 14      patients that are reported in this study 15      beyond yourself?</p> <p>16            MR. JACKSON: Objection, form.</p> <p>17   A. There would have been some other physicians 18      under my, I would say under my encouragement 19      and direction who would have treated patients 20      in this investigation.</p> <p>21   Q. And this investigation, did it all occur at 22      Brigham &amp; Women's?</p> <p>23   A. Yes.</p> <p>24   Q. And those physicians that you would have 25      encouraged, were they within your group</p>
<p style="text-align: right;">Page 43</p> <p>1       "reducing undesirable alterations and 2       perfusion"?</p> <p>3            MR. JACKSON: Objection, calls for 4       expert testimony.</p> <p>5   A. Again, the idea was it was not likely to 6      reverse what the lung is trying to do and 7      make oxygenation worse.</p> <p>8   Q. So in this abstract you're indicating that 9      if you used an inhaled treprostinil therapy, 10     you can avoid this V/Q mismatch because 11      the vasodilator is not vasodilating 12      indiscriminately, but specifically in the 13      site that you want it to?</p> <p>14            MR. JACKSON: Objection, calls for 15      expert testimony.</p> <p>16   A. I would say more selectively.</p> <p>17   Q. More selectively in the areas that you would 18      want the vasodilation to occur?</p> <p>19            MR. JACKSON: Same objection.</p> <p>20   A. Yes.</p> <p>21   Q. The next sentence says, "we conducted." 22      Does that include yourself?</p> <p>23   A. Yes.</p> <p>24   Q. Who else is the "we"?</p> <p>25   A. Well, I have a team that works with me,</p>	<p style="text-align: right;">Page 45</p> <p>1       or were they in the general practice at 2       Brigham &amp; Women's?</p> <p>3            MR. JACKSON: Objection, form.</p> <p>4   A. They were within the pulmonary vascular 5      group.</p> <p>6   Q. Were you the head of the group at that time 7      in 2015 and earlier?</p> <p>8   A. Yes.</p> <p>9   Q. Do you recall the time frame in which these 10     patients were treated?</p> <p>11   A. I don't remember exactly.</p> <p>12   Q. [REDACTED]</p> <p>13   [REDACTED]</p> <p>14   [REDACTED]</p> <p>15   [REDACTED]</p> <p>16   A. [REDACTED]</p> <p>17   Q. Going back to the sentence that says, "we 18      conducted a retrospective assessment of 19      Group-3 PH patients receiving inhaled 20      treprostinil to investigate the effects of 21      inhaled treprostinil on dyspnea" --</p> <p>22   A. "Dyspnea."</p> <p>23   Q. "Dyspnea." I apologize. It will sound 24      perfect on the transcript. "Six-minute walk 25      distance BDI and WHO FC"?</p>

1           MR. JACKSON: Objection to form. 2   A. Yes. 3   Q. What is a retrospective assessment? 4   A. It's a look backwards. It's a review of 5   medical records. 6   Q. So if I understand correctly, patients, 7   looking at this sentence, patients in Group-3 8   who were on inhaled treprostinil at Brigham & 9   Women's for some period of time prior to 10   2014, you had their medical records available 11   to you, is that right? 12           MR. JACKSON: Objection, form, calls 13   for a legal conclusion. 14   A. They were our patients, so yes, we had the 15   medical records. 16   Q. And in doing this retrospective assessment, 17   did you look at those medical records to 18   aggregate the data that's reflected in the 19   abstract? 20           MR. JACKSON: Objection to form. 21   A. Yes. 22   Q. [REDACTED] 23   [REDACTED] 24   [REDACTED] 25           MR. JACKSON: Objection, form.	Page 46	1   Iloprost, correct? 2   A. Yes. 3   Q. [REDACTED] 4   [REDACTED] 5           MR. JACKSON: Objection to form. 6   A. [REDACTED] 7   Q. [REDACTED] 8   [REDACTED] 9   A. [REDACTED] 10   Q. So, again, the "we" at Brigham & Women's 11   and yourself, not speaking for everybody 12   else in the world, but for yourself at least, 13   [REDACTED] 14   [REDACTED] 15   A. [REDACTED]. 16   Q. [REDACTED] r 17   [REDACTED] 18   A. [REDACTED] 19   Q. [REDACTED] 20   [REDACTED] 21   A. [REDACTED] 22   Q. And you understand that Tyvaso was originally 23   approved with the indication to improve 24   exercise capacity in Group-1 PAH patients? 25           MR. JACKSON: Objection, form, calls	Page 48
1   A. [REDACTED] 2   Q. [REDACTED] 3   [REDACTED] 4   A. [REDACTED] 5   Q. [REDACTED] 6   [REDACTED] 7   [REDACTED] 8           MR. JACKSON: Objection, form. 9   A. [REDACTED] 10   [REDACTED] 11   Q. [REDACTED] 12   [REDACTED] 13   [REDACTED] 14   A. [REDACTED] 15   [REDACTED] 16   [REDACTED] 17   Q. [REDACTED] 18   [REDACTED] 19           MR. JACKSON: Objection, form. 20   A. [REDACTED] 21   [REDACTED] 22   [REDACTED] 23   Q. You understand that in 2014 and earlier 24   there was another prostanoid available to 25   be administered by the inhaled group called	Page 47	1   for expert testimony and calls for a 2   legal conclusion. 3   A. Again, in my opinion, it was exercise 4   tolerance, not capacity, but yes. 5   Q. In your mind, is there a difference between 6   exercise tolerance and exercise capacity? 7   A. Yes. 8   Q. What is that difference? 9   A. One is a measure of the physiologic response, 10   that would be capacity, and exercise 11   tolerance is the ability of the patient to 12   exercise. 13   Q. How do you measure capacity versus measuring 14   tolerance? 15           MR. JACKSON: Objection, calls for 16   expert testimony. 17   A. The way we do it in medicine in general 18   and physiology in general is that we would 19   use a metabolic cart which would measure a 20   patient's gas exchange, their oxygen uptake, 21   their CO2 production while they exercise. 22   Q. In this abstract with respect to the 23   statement we read on the retrospective 24   assessment using inhaled treprostinil for 25   these Group-3 patients, do you recall, did	Page 49

<p style="text-align: right;">Page 222</p> <p>1           MR. SUKDUANG: I don't have any      2        questions, additional questions at this time.      3        I appreciate your time. Maybe counsel has      4        some that they look like they typed out and      5        prepared for you.</p> <p>6           MR. JACKSON: I only have a few      7        questions for you.</p> <p>8           CROSS EXAMINATION</p> <p>9           BY MR. JACKSON:</p> <p>10          Q. Do you remember when counsel for Liquidia      11        asked you about your role in the INCREASE      12        trial earlier today?</p> <p>13          A. Yes.</p> <p>14          Q. Do you remember when you talked about      15        learning of the results of the INCREASE      16        trial?</p> <p>17          A. Yes.</p> <p>18          Q. Not the unblinded results, but just when      19        you learned of the results of the trial,      20        correct?</p> <p>21          A. Correct.</p> <p>22          Q. You recall that's a clarification that we      23        discussed earlier today, right?</p> <p>24          A. Yes.</p> <p>25          Q. Do you recall when about that was, the</p>	<p style="text-align: right;">Page 224</p> <p>1        your hypothesis was right or wrong, how      2        did you feel?</p> <p>3          A. I was petrified.</p> <p>4          Q. And why were you petrified?</p> <p>5          A. I hate being wrong and it was a huge      6        investment on UT's part to do the clinical      7        trial, and also just the fact that I was      8        convinced all these patients were doing      9        well on a placebo-controlled trial and if      10       it was all placebo effect, it wouldn't be      11       a good thing.</p> <p>12          Q. Do you recall when counsel for Liquidia      13        asked you some questions about the use of      14        Tyvaso in PH-ILD patients?</p> <p>15          A. Yes.</p> <p>16          Q. In the retrospective study that we've      17        been, that counsel has been directing your      18        attention to several times, you said you      19        used Tyvaso for certain PH-ILD patients,      20        is that right?</p> <p>21          A. Yes.</p> <p>22          Q. The population that you used it for, is      23        that the same population as was in the      24        INCREASE trial?</p> <p>25          A. Pretty much, yes.</p>
<p style="text-align: right;">Page 223</p> <p>1        approximate date?</p> <p>2          A. I don't.</p> <p>3          Q. Would it be sometime around 2022 or so?</p> <p>4           MR. SUKDUANG: Objection, calls for      5        speculation.</p> <p>6          A. That would have been when we wrote the paper      7        and published the paper.</p> <p>8          Q. With that in mind, then, how much before      9        that did you learn about the results?</p> <p>10         A. It took a long time to write the paper and      11        to get it accepted, so it probably might      12        have been more than a year.</p> <p>13         Q. So maybe more like February of 2020?</p> <p>14           MR. SUKDUANG: Calls for      15        speculation.</p> <p>16         A. Possibly.</p> <p>17         Q. What do you remember about the day when      18        you learned the results of the INCREASE      19        trial?</p> <p>20         A. When you get the call on a clinical trial,      21        it's kind of nail-biting because you don't      22        know if you were right or wrong, and I was      23        overjoyed to hear we were, our hypothesis      24        was right.</p> <p>25         Q. And immediately before learning whether</p>	<p style="text-align: right;">Page 225</p> <p>1        Q. Were there differences between those two      2        populations?</p> <p>3          A. We probably saw predominantly what's called      4        UIP, usual interstitial pneumonia. They all      5        overlap, but I don't think it was a big      6        difference.</p> <p>7          Q. But the differences might be in the PAP      8        numbers or the --</p> <p>9          A. Oh, the --</p> <p>10         MR. SUKDUANG: Hold on. Let him      11        finish his question. I'm going to object,      12        so let him finish the question.</p> <p>13         Q. Did the various individuals you were using      14        in the retrospective study and the      15        individuals in the INCREASE trial match in      16        terms of the PAP numbers, the median PAP      17        numbers?</p> <p>18         MR. SUKDUANG: Asked and answered,      19        calls for speculation, calls for expert      20        testimony.</p> <p>21         A. The population that we treated and wrote      22        up and presented about were probably a more      23        advanced, sicker group of patients.</p> <p>24         Q. Were you aware of others using Tyvaso -- at      25        the time of your retrospective study, were</p>

<p style="text-align: right;">Page 226</p> <p>1 you aware of anyone else using Tyvaso for      2 PH-ILD patients?</p> <p>3 A. I knew of a few people.</p> <p>4 Q. Did you ever discuss with other physicians      5 your idea of using or the concept of using      6 Tyvaso for PH-ILD patients?</p> <p>7 A. I'm sure I did. I don't remember any      8 specific conversations, but just knowing      9 that there were people doing what I was      10 doing.</p> <p>11 Q. Did you ever raise it and get negative      12 reactions from any other physicians in the      13 field?</p> <p>14 A. There are definitely some very narrow-minded      15 conservative physicians out there that if      16 you deviate from the guidelines, you aren't      17 doing the right thing.</p> <p>18 Q. Do you recall when we were looking earlier      19 at -- sorry. Earlier today counsel directed      20 you to -- early on. Let's see.      21       I think it was Waxman -- let's look      22 at Waxman 3. Are you there?</p> <p>23 A. Yes.</p> <p>24 Q. Do you recall when counsel for Liquidia      25 asked you questions about the change in the</p>	<p style="text-align: right;">Page 228</p> <p>1 A. Yes.</p> <p>2 Q. Did this abstract report a p-value with      3 respect to PH-ILD patients treated with      4 Tyvaso?</p> <p>5           MR. SUKDUANG: Calls for expert      6 testimony.</p> <p>7 A. Not specifically, no.</p> <p>8 Q. Did this abstract involve a study with a      9 placebo-controlled arm?</p> <p>10 A. No.</p> <p>11 Q. So from the data reported -- actually, let      12 me shift gears quickly to -- you also looked      13 at -- let's look at Waxman 6. Are you there      14 with me?</p> <p>15 A. Yes.</p> <p>16 Q. You remember when counsel asked you questions      17 about this document and about the six-minute      18 walk distance reported in this document,      19 correct?</p> <p>20 A. Yes.</p> <p>21 Q. Let's take a look at the first page. Did      22 this publication report a p-value for the      23 aggregate patient population in terms of the      24 change in six-minute walk distance?</p> <p>25           MR. SUKDUANG: Calls for expert</p>
<p style="text-align: right;">Page 227</p> <p>1 six-minute walk distance reported in this      2 abstract?</p> <p>3 A. Yes.</p> <p>4 Q. And did this abstract identify a p-value      5 for the six-minute walk distance in the      6 aggregate patient population?</p> <p>7 A. For the --      8           MR. SUKDUANG: Objection. The      9 document speaks for itself and asked and      10 answered.</p> <p>11 A. For the aggregate, yes.</p> <p>12 Q. And what is the p-value for the aggregate?</p> <p>13           MR. SUKDUANG: Is this expert      14 testimony that you're seeking?</p> <p>15 Q. I'm asking what does the document read.</p> <p>16 What's the p-value listed in this document      17 for the change in six-minute walk distance?</p> <p>18           MR. SUKDUANG: Based on UTC's prior      19 objection regarding this document, calls for      20 expert testimony. You can go ahead and      21 answer.</p> <p>22 A. The p-value for the cohort is .0019.</p> <p>23 Q. And earlier today you will recall counsel      24 for Liquidia asked you about p-values,      25 correct?</p>	<p style="text-align: right;">Page 229</p> <p>1 testimony.</p> <p>2 A. It did.</p> <p>3 Q. What was that number?</p> <p>4 A. P-value was .022.</p> <p>5 Q. And what patients were included in the      6 population that had that p-value of .022?</p> <p>7 A. This was the cohort so it included patients      8 with PH-COPD and PH-ILD and combined      9 pulmonary fibrosis and emphysema.</p> <p>10 Q. Did this document identify a p-value with      11 respect to the PH-ILD patients treated      12 with Tyvaso?</p> <p>13           MR. SUKDUANG: Calls for expert      14 testimony.</p> <p>15 A. No.</p> <p>16 Q. Did the data underlying this document      17 involve a placebo-controlled arm?</p> <p>18 A. No.</p> <p>19           MR. JACKSON: I have no further      20 questions and I appreciate your time today.</p> <p>21           REDIRECT EXAMINATION</p> <p>22 BY MR. SUKDUANG:</p> <p>23 Q. [REDACTED]</p> <p>24 [REDACTED]</p> <p>25 [REDACTED]</p>

<p style="text-align: right;">Page 230</p> <p>1 [REDACTED] 2 [REDACTED] 3 MR. JACKSON: Objection to form. 4 A. In part. 5 Q. [REDACTED] 6 [REDACTED] 7 [REDACTED] 8 A. Correct. 9 Q. [REDACTED] 10 [REDACTED] 11 [REDACTED] 12 [REDACTED] 13 MR. JACKSON: Objection to form, 14 calls for expert testimony and goes beyond 15 the scope of redirect. 16 A. [REDACTED] 17 [REDACTED] 18 [REDACTED] 19 Q. [REDACTED] 20 [REDACTED] 21 [REDACTED] 22 [REDACTED] 23 MR. JACKSON: Same objections. 24 A. [REDACTED] 25 [REDACTED]</p> <p style="text-align: right;">Page 231</p> <p>1 Q. [REDACTED] 2 [REDACTED] 3 [REDACTED] 4 [REDACTED] 5 MR. JACKSON: Objection to form. 6 A. [REDACTED] 7 Q. And that -- no further questions. I 8 appreciate your time. Thank you. 9 MR. JACKSON: I have nothing further 10 as well. Thank you for your time. 11 VIDEOGRAPHER: The time is 4:01 p.m. 12 We're off the record. 13 (Whereupon the deposition was 14 concluded at 4:01 p.m.) 15 16 17 18 19 20 21 22 23 24 25</p>	<p style="text-align: right;">Page 232</p> <p>1 COMMONWEALTH OF MASSACHUSETTS) 2 SUFFOLK, SS. ) 3 4 I, Jeanette Maracas, Registered 5 Professional Reporter and Notary Public in and for the Commonwealth of Massachusetts, 6 do hereby certify that there came before me on the 12th day of December, 2024, at 9:05 7 a.m., the person hereinbefore named, who was by me duly sworn to testify to the truth 8 and nothing but the truth of his knowledge touching and concerning the matters in 9 controversy in this cause; that he was thereupon examined upon his oath, and his 10 examination reduced to typewriting under my direction; and that the deposition is a true record of the testimony given by the witness. 11 12 I further certify that I am neither 13 attorney or counsel for, nor related to or employed by, any attorney or counsel employed 14 by the parties hereto or financially interested in the action. 15 16 In witness whereof, I have hereunto set my hand this 16th day of December, 2024. 17 18 19 20  My commission expires 7/29/27 21 22 23 24 25</p> <p style="text-align: right;">Page 233</p> <p>1 William Jackson, Esq. 2 wjackson@goodwinlaw.com 3 December 16, 2024 4 RE: United Therapeutics Corporation v. Liquidia Technologies 5 12/12/2024, Aaron B. Waxman , M.D. (#7045829) 6 The above-referenced transcript is available for 7 review. 8 Within the applicable timeframe, the witness should 9 read the testimony to verify its accuracy. If there are 10 any changes, the witness should note those with the 11 reason, on the attached Errata Sheet. 12 The witness should sign the Acknowledgment of 13 Deponent and Errata and return to the deposing attorney. 14 Copies should be sent to all counsel, and to Veritext at 15 cs-midatlantic@veritext.com. 16 Return completed errata within 30 days from 17 receipt of testimony. 18 If the witness fails to do so within the time 19 allotted, the transcript may be used as if signed. 20 21 22 Yours, 23 Veritext Legal Solutions 24 25</p>
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# EXHIBIT 6

1 IN THE UNITED STATES DISTRICT COURT  
2 IN AND FOR THE DISTRICT OF DELAWARE  
3  
4 UNITED THERAPEUTICS CORPORATION, )  
5 -----Plaintiff, ) Case No.  
6 vs. ) 23-CV-975-RGA-SRF  
7 LIQUIDIA TECHNOLOGIES, INC., )  
8 -----Defendant. )

## 9 TRANSCRIPT OF MOTION TO EXTEND DEADLINES

10 MOTION TO EXTEND DEADLINES had before the Honorable  
11 Sherry R. Fallon, U.S.M.J., via teleconference on the 5th of  
12 December, 2024.

## 13 APPEARANCES

14 MORRIS, NICHOLS, ARSH & TUNNELL LLP  
15 BY: CAMERON CLARK, ESQ.  
16 -and-

17 McDERMOTT WILL & EMERY  
18 BY: DOUG CARSTEN, ESQ.  
ADAM BURROWBRIDGE, ESQ.

19 Counsel for Plaintiff

20 SHAW KELLER LLP  
21 BY: KAREN KELLER, ESQ.  
22 -and-

23 COOLEY LLP  
24 BY: SANYA SUKDUANG, ESQ.  
25 Counsel for Defendant

1 will proceed.

2 This is the second time I'm presented with a  
3 motion to extend certain deadlines in the case schedule, and  
4 that's one of the reasons that prompted me to schedule an  
5 in-person conference in the first place. Nonetheless, here  
6 we are, and I am ready to proceed.

7 Liquidia is the movant on this motion, so I'll  
8 hear from Liquidia first.

9 MR. SUKDUANG: Good afternoon, Your Honor. This  
10 is Sanya Sukduang. I just want to confirm you can hear me.

11 THE COURT: I can hear you. Thank you. And if  
12 anyone has any difficulty hearing me, as the Court recently  
13 switched media platforms to do these conference calls,  
14 please let me know or dial into chambers or e-mail chambers.  
15 Ms. Hicks is at her computer and can get e-mails from  
16 counsel if we have any difficulties going along. So thank  
17 you.

18 MR. SUKDUANG: Thank you, Your Honor. If it's  
19 okay, I'll begin again. This is Sanya Sukduang from Cooley  
20 on behalf of Liquidia, and we appreciate you taking some  
21 time to hear some argument regarding our pending motions.

22 This is the second motion Liquidia has filed to  
23 extend certain deadlines. We don't take these motions  
24 lightly, Your Honor, and only move in situations where we  
25 believe the schedule necessitates some movement in

2

1 THE COURT: This is Magistrate Judge Sherry  
2 Fallon. I am joining the call in *UTC, United Therapeutics*  
3 *Corporation, versus Liquidia*. I'm going to start by  
4 confirming that everyone who is planning to participate in  
5 this call is on the line. Let's start with appearances of  
6 counsel.

7 Who is on the line for United Therapeutics  
8 Corporation?

9 MR. CLARK: Good afternoon, Your Honor. This is  
10 Cameron Clark from Morris Nichols on behalf of United  
11 Therapeutics, and joining me on the call today are Doug  
12 Carsten and Adam Burrowbridge from McDermott Will & Emery,  
13 and Mr. Burrowbridge will be addressing the Court today.

14 THE COURT: Thank you. And now let me hear who  
15 is on the line for Liquidia.

16 MS. KELLER: Good afternoon, Your Honor. It's  
17 Karen Keller from Shaw Keller, and with me on the line who  
18 will be handling the argument is Sanya Sukduang from Cooley.

19 THE COURT: Okay. Thank you.

20 First of all, I want to thank everyone for  
21 flexibility in converting this to a teleconference. I had  
22 hoped to see all of you in person, but building mechanics  
23 did not cooperate. Apparently, there's a broken water main,  
24 and it was necessary to close the courthouse today in order  
25 for the necessary repairs to be made. But in any event, we

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1 deadlines.

2 In this particular instance, we're looking to  
3 move the deadline for serving expert reports in this case.  
4 As you saw in our motion, one of our key witnesses that we  
5 intend or will depose is Dr. Aaron Waxman. His deposition  
6 was provided to us on November 11th. That was after the  
7 parties had submitted their letters to the Court regarding  
8 the first motion to extend and only a few hours before the  
9 Court denied that prior motion.

10 Dr. Waxman is a practicing physician. He wrote  
11 prior art articles regarding treatment of pulmonary  
12 hypertension associated with interstitial lung disease or  
13 PHILD with Tyvaso years before the claimed subject matter.  
14 Depositions in this case have made it clear that Dr. Waxman,  
15 again, is more than the prior author. He's the conceiver of  
16 the claimed invention which is formed around the increase  
17 trial and his deposition date is the day before expert  
18 reports are due.

19 Expert reports are due on September 13th. His  
20 deposition is on the 12th, and under the current schedule,  
21 Liquidia is required to not only prepare for his deposition  
22 but also submit expert reports at the same time.

23 This is not a situation where or -- United  
24 Therapeutics would be surprised by our request. We had  
25 asked for Dr. Waxman's deposition starting, I think, on

1 opportunity, explored these issues with the witnesses  
2 available to us, and they keep pointing back to  
3 Dr. Rothblatt herself.

4 THE COURT: How do we account for a deposition  
5 if the Court were inclined to grant a few hours with her  
6 without disrupting the order I entered to push out expert  
7 reports by a week?

8 (Cross-talk.)

9 MR. SUKDUANG: I'd have to leave that to UTC  
10 with respect to Dr. Rothblatt's availability. This is a  
11 situation where we have been asking for Dr. Rothblatt's  
12 deposition for a very long time, and I do appreciate the  
13 extension of the expert discovery, but part of it depends on  
14 when UTC makes Dr. Rothblatt available.

15 THE COURT: All right.

16 UTC, you wanted to address that.

17 MR. BURROWBRIDGE: Well, I wanted to address  
18 something that counsel said earlier.

19 This new e-mail argument is brand new, as Your  
20 Honor mentioned. It's not in their papers. They don't have  
21 any exhibits of these e-mails that they're referring to, so  
22 it's hard to concretely address the issues that counsel's  
23 raising for the very first time on this call. These issues  
24 were never raised in the meet-and-confer. They're not  
25 raised in the moving letter. And, again, the apex doctrine

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1 bars this exact type of deposition with a high-ranking  
2 corporate official.

3 With regard to the people in the motion, these  
4 are people they have deposed or could have deposed. These  
5 are other individuals who share the same common knowledge  
6 that they allege Dr. Rothblatt to have, yet for some reason  
7 they say it must and it's critical for their case to depose  
8 Dr. Rothblatt. That's also at odds with their prior  
9 willingness to not depose Dr. Rothblatt in exchange for an  
10 extension to the expert discovery schedule.

11 We're hearing a lot of new things on this call,  
12 which is unsettling for several reasons, but I don't see how  
13 we could make time in the schedule for additional fact  
14 discovery when fact discovery has been closed and this issue  
15 has been raised and decided.

16 MR. SUKDUANG: Your Honor, I apologize.

17 Mr. Burrowbridge is incorrect. We did cite to  
18 one of the e-mails. It's Exhibit 25 to our letter.  
19 Dr. Rothblatt to Roger Jeffs talking about these  
20 conversations with Dr. Capstan and Dr. Sagar.

21 THE COURT: The issues that are being raised on  
22 the call are issues that are not -- have not been vetted  
23 between the parties through a meet-and-confer and should  
24 have been vetted on the first go-round before asking for the  
25 deposition of Dr. Rothblatt for the first time.

1 All of you on this call know who's entitled to  
2 see what information under the protective order. As has  
3 been stated on this call, this issue of prior public use of  
4 Tyvaso has been a critical issue running through the course  
5 of the litigation. It's certainly a topic that doesn't take  
6 anyone by surprise, and if there are particular witnesses  
7 necessary to explore that topic going right up to the top  
8 with Dr. Rothblatt, presumably that would have been known  
9 and vetted through a meaningful meet-and-confer process  
10 previously.

11 I've just extended expert discovery so that  
12 Dr. Waxman's testimony could be taken into consideration in  
13 connection with separation of expert reports. Allowing  
14 Dr. Rothblatt would completely undermine that, so I have to  
15 say on this call I am not satisfied that there is anything  
16 new and dramatically -- that dramatically alters the status  
17 of what was provided to me when I first ruled against  
18 allowing Dr. Rothblatt's deposition, and the failure of a  
19 meaningful meet-and-confer process should not be then thrust  
20 on the Court in a manner that now the Court is faced with a  
21 problem with literally no time in the schedule to get in  
22 this witness.

23 So under the circumstances, I have to say that  
24 this is new information. It wasn't properly vetted with a  
25 meaningful meet-and-confer process. That process was not

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1 utilized as it should have been with regard to this witness,  
2 who is undisputedly an apex witness. For all of those  
3 reasons, I'm going to deny the request for a deposition of  
4 Dr. Rothblatt.

5 But before we all leave the call, I want to  
6 address the very next dispute that has come my way recently,  
7 the request to deal with inequitable conduct and to strike  
8 certain allegations relating to that and the invalidity  
9 contentions. I want to discuss the format of how the Court  
10 is going to brief that.

11 But before I get into procedure on that, let me  
12 ask the parties starting with Liquidia, is there anything  
13 further that the Court needs to address with respect to the  
14 pending motion to extend the scheduling deadlines that I've  
15 ruled on and the Dr. Rothblatt deposition?

16 MR. SUKDUANG: Only -- well, yes, two things  
17 with respect to Dr. Rothblatt, Your Honor.

18 One, I know you believe we did not have a  
19 meaningful meet-and-confer. We are in front of this Court  
20 quite a bit. We do have highly respected local counsel in  
21 the Shaw Keller team. We believe we did a meaningful  
22 meet-and-confer. We brought these issues before. I  
23 understand the Court's ruling. I'm not going to dispute  
24 that, but I want to make -- we believe we have and certainly  
25 local counsel has made us aware of our obligations to do

1 prejudice, again, should things -- the landscape change and  
 2 the parties see a need to bring that before the Court.

3 With respect to any other disputes that are  
 4 brewing, be mindful of the time constraints left in the  
 5 schedule. I don't know how to say this otherwise other than  
 6 pick your battles and to try and work them out as best you  
 7 can and, certainly, if the parties can't work them out  
 8 themselves, then the issue will be brought back to the  
 9 Court.

10 In all likelihood, I will schedule a time to do  
 11 an in-person hearing, and I will hope that no further  
 12 building catastrophes occur to prevent that from happening,  
 13 but I think the value of in-person, particularly when we've  
 14 had this many disputes, is it gives counsel an opportunity  
 15 to talk a little bit more while you're waiting for me to  
 16 take the bench and then gives us all an opportunity to have  
 17 an open dialogue that's a little bit easier to engage in  
 18 than when we're doing it electronically like this. Bear  
 19 that in mind.

20 Also, while I do stand on procedures and  
 21 formalities and such, I understand that there are practical  
 22 concerns, so feel free when you brief these matters that if  
 23 there are practicalities that may -- you'd like the Court to  
 24 take into consideration along with the legal authorities and  
 25 other information you're going to pass on to me, just feel

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 1 free to include that because I say this frequently in  
 2 discovery disputes, that my aim is to make sure that each  
 3 side has what it needs to effectively prepare its case in  
 4 chief for trial and that the discovery, both fact and  
 5 expert, progresses in a manner that provides that  
 6 information.

7 And also I'm mindful all the time of the  
 8 deadlines in the scheduling deadlines because I do not want  
 9 to jam up the district judge or important to all of you and  
 10 your clients in the case, particularly when we get down to  
 11 the wire up to the pretrial conference and trial. So that's  
 12 my view typically in these cases.

13 And that's also a reason that in many instances  
 14 where I find that the disputes can be resolved on the  
 15 papers, that I don't think there's details that I need to be  
 16 told that are outside of the papers, that I try to resolve  
 17 them on the papers when possible so as to keep the case  
 18 flowing. So there you have it.

19 Does anyone else have any questions? Let me  
 20 hear first from the plaintiff, UTC.

21 MR. BURROWBRIDGE: Nothing from UTC. Thank you,  
 22 Your Honor.

23 THE COURT: From Liquidia?

24 MR. SUKDUANG: Nothing, Your Honor. Thank you.

25 THE COURT: All right. Thank you, counsel. I'm

1 signing off now. Take care.

2

3

4 C E R T I F I C A T E

5 I, Deanna L. Warner, a Registered Professional  
 6 Reporter, do hereby certify that as such Registered  
 7 Professional Reporter, I was present at and reported in  
 8 Stenotype shorthand the above and foregoing proceedings.

9

10

Deanna L. Warner, RPR, CSR  
 Official Court Reporter  
 U.S. District Court

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# EXHIBIT 7

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS  
CORPORATION,

Plaintiff,

v.

LIQUIDIA TECHNOLOGIES, INC.,

Defendant.

C.A. No. 1:23-cv-00975-RGA

[REDACTED]

**DEFENDANT LIQUIDIA TECHNOLOGIES, INC.'S  
INITIAL INVALIDITY CONTENTIONS**

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### 3. Long Before April 2020, Physicians Were Using Inhaled Treprostinil to Treat PH-ILD

While Tyvaso® was approved for PH-ILD in 2021, the idea and demonstrated success of using treprostinil, including inhaled treprostinil, in Group 3 patients, including PH-ILD patients, predates both Tyvaso®’s approval date for PH-ILD as well as the April 17, 2020 filing date of the ’327 patent. Indeed, the idea of treating Group 3 PH, including PH-ILD, by using inhaled prostacyclin, was shown to be safe as early as 1999. (H. Olschewski, et al., Inhaled Prostacyclin and Iloprost in Severe Pulmonary Hypertension Secondary to Lung Fibrosis, *Am. J. Respir. Crit. Care. Med.* 160:600-607 (1999) (LIQ\_PH-ILD\_00002398) (“Olschewski 1999”).)

Multiple studies reported positive uses of treprostinil in WHO Group 3 patients, including those with PH-ILD. For example, in 2009 in a study supported by a UTC research grant, Saggar, et al. reported that a patient who was administered parenteral treprostinil showed improvement in the 6MWD, WHO functional class, BNP level, quality of life survey score, Borg Dyspnea Scale, and spirometric function, including an improvement in FVC (% predicted). (R. Saggar, et al., Treprostinil to Reverse Pulmonary Hypertension Associated with Idiopathic Pulmonary Fibrosis as a Bridge to Single-Lung Transplantation, *J. Heart and Lung Transplant.* 28:964-7 (2009) (LIQ\_PH-ILD\_00002986) (“Saggar 2009”) at LIQ\_PH-ILD\_00002987.)

In 2014, in another study funded partly by UTC, Saggar et al. examined, amongst other things, hemodynamics, 6MWD, and quality of life indices in patients with pulmonary fibrosis (a form of PH-ILD) who were administered parenteral treprostinil. (See Saggar 2014 at LIQ\_PH-ILD\_00000226.) The authors reported “significant improvements in right heart h[e]modynamics,” “improvements [] in 6MWD,” improvements in quality of life indices as measured in the 36-Item Short Form Health Survey Mental Component Summary aggregate and the University of California San Diego Shortness of Breath Questionnaires, and improvements in BNP levels. (Saggar 2014 at LIQ\_PH-ILD\_00000226, LIQ\_PH-ILD\_00000228 (Tbl. 2), LIQ\_PH-

ILD\_00000229, LIQ\_PH-ILD\_00000231.) The study also indicated an improvement in FVC, % predicted following treprostinil treatment. (*Id.* at LIQ\_PH-ILD\_00000228 (Tbl. 2).)

Similarly, a 2012 patent publication from UTC claimed, “[a] method of treating a condition associated with an interstitial lung disease, comprising parenteral administration to subject in need thereof an effective amount of [t]reprostinil. . . wherein said condition is pulmonary hypertension, which [is] a complication of said interstitial lung disease.” (US 2013/0096200 (UTC\_PH-ILD\_010774) (“Wade 200”) at cl. 1.) The patent disclosed studies showing a positive effect of intravenous treprostinil in patients with IPF and PH. (*Id.* at [0082].)

Several studies further demonstrated that inhaled treprostinil was effective (including in improving exercise capacity) in Group 3 PH, including PH-ILD. In 2011, Schirro and Waxman described that inhaled treprostinil, delivered according to the “usual protocol starting with three breaths four times a day,” in patients with PH and parenchymal lung disease (a form of Group 3 PH) showed improvements in the 6MWD and on the Borg Dyspnea Scale. (A. Schirro and A. Waxman, Inhaled treprostinil therapy in patients with pulmonary hypertension and parenchymal lung disease, *Eur. Respir. J.* 38:p2385 (2011) (LIQ\_PH-ILD\_00002474) (“Schirro and Waxman 2011”) at Abstract; *see also* *Eur. Respir. J.* Vol. 38 Suppl. 55 Table of Contents (LIQ\_PH-ILD\_00002462).) The authors concluded that inhaled treprostinil “may offer an effective and well tolerated treatment in subjects with PLD and shortness of breath exacerbated by PH.” (*Id.*)

In 2015, Agarwal and Waxman examined inhaled treprostinil in WHO Group-3 PH patients, including patients with restrictive disease, and saw significant improvements in the 6MWD. (M. Agarwal and A.B. Waxman, Inhaled Treprostinil in Group-3 Pulmonary Hypertension, *J. Heart and Lung Transplant.* 34(4):S343 (2015) (UTC\_PH-ILD\_009828) (“Agarwal 2015”).) The authors concluded that “Group-3 PH can be effectively and safely treated” with inhaled treprostinil and that “[i]nhaled [t]reprostinil may offer a well-tolerated

treatment in advanced lung disease patients complicated by pulmonary vascular remodeling.” (Agarwal 2015 at UTC\_PH-ILD\_009828 (Conclusion).)

In 2016, researchers in a UTC funded study reviewed 6MWD data from WHO Group 1–5 patients treated with inhaled treprostinil and reported an improvement in the 6MWD in the retrospective study, including in patients with PH-ILD. (K. Parikh, et al., Safety and Tolerability of High-dose Inhaled Treprostinil in Pulmonary Hypertension, *J. Cardiovasc. Pharmacol.* 67(4): 322-25 (2016) (UTC\_PH-ILD\_010599) (“Parikh 2016); *see also* (LIQ\_PH-ILD\_00002439).)

Then again, in 2018, Faria-Urbina and colleagues looked at 22 patients with PH-associated with lung disease who were treated with inhaled treprostinil. (M. Faria-Urbina, et al., Inhaled Treprostinil in Pulmonary Hypertension Associated with Lung Disease, *Lung* 196:139-46 (2018) (UTC\_PH-ILD\_009936) (“Faria-Urbina 2018”)). Their assessment concluded that Group 3-PH patients treated with inhaled treprostinil saw significant improvements in the 6MWD.

On the basis of the positive studies described above and the rationale for using inhaled treprostinil in PH-ILD patients, physicians, regularly prescribed inhaled treprostinil to PH-ILD patients off-label.<sup>3</sup> They did so before the April 2020 filing date of the ’327 patent, before the results of the INCREASE trial were published, and before Tyvaso® was approved for the treatment of PH-ILD. Physicians started prescribing Tyvaso® to PH-ILD patients almost immediately after it was approved in 2009, and did so according to the dosing regimen described

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<sup>3</sup> A 2015 survey of 30 U.S. pulmonary vascular disease centers used PAH therapy in patients with non-group 1 PH, including treprostinil. (A. W. Trammell, et al., Use of pulmonary arterial hypertension-approved therapy in the treatment of non-group 1 pulmonary hypertension at US referral centers, *Pulm. Circ.* 5(2):356-63 (2015) (LIQ\_PH-ILD\_00002539) (“Trammel 2015”).) In 2017, the Giessen PH registry showed that 78% of WHO Group 3 patients, including PH-ILD patients, were on PAH therapies. (H. Gall, et al., The Giessen Pulmonary Hypertension Registry: Survival in pulmonary hypertension subgroups, *J. Heart Lung Transplant.* 36(9):957-67 (2017) (LIQ\_PH-ILD\_00001617) (“Gall 2017”) at 965.)

in the Tyvaso® label. (D.I. 54 (“Channick Decl.”), ¶52.) Even UTC’s expert, Dr. Steven Nathan, acknowledged that he likely used inhaled treprostinil off-label to treat PH-ILD patients, and certainly used another therapy, sildenafil, to treat PH-ILD off-label. (Nathan Dep. Tr. at 88:19-89:21, 92:15-20, 96:6-8.)

#### **4. The INCREASE Study Confirmed Known Benefits of Inhaled Treprostinil in PH-ILD Patients**

The studies described above also formed the rationale and motivation for the design and conduct of the INCREASE study, which was a large clinical study for inhaled treprostinil in PH-ILD patients that began in 2015. (Waxman 2021 at UTC\_PH-ILD\_010790-829.) In particular, the New England Journal of Medicine publication for the INCREASE study cited to several of the studies noting

Data from previously completed pilot studies suggest that inhaled treprostinil can improve hemodynamics and functional capacity in patients with group 3 pulmonary hypertension. Therefore, the objective of the INCREASE trial was to evaluate the safety and efficacy of inhaled treprostinil in patients with [PH-ILD].

(*Id.* at UTC\_PH-ILD\_010791, UTC\_PH-ILD\_010799 (citing Agarwal 2015, Faria-Urbina 2018, L. Wang, et al., Hemodynamic and gas exchange effects of inhaled iloprost in patients with COPD and pulmonary hypertension, *Int'l J. COPD*, 12:3353-60 (2017) (UTC\_PH-ILD\_010782), and A. Bajwa, et al., The safety and tolerability of inhaled treprostinil in patients with pulmonary hypertension and chronic obstructive pulmonary disease, *Pulmonary Circulation* 7:82-88 (2017) (UTC\_PH-ILD\_009846).)

The INCREASE results were published in 2021 and confirmed the results seen in earlier studies that treprostinil administered to patients with PH-ILD “improved exercise capacity from baseline, assessed with the use of a 6-minute walk test.” (Waxman 2021 at UTC\_PH-ILD\_010790 (Abstract).) The authors reported a change of 31.12 meters from baseline in six-minute walk distance over the 16 weeks with a 95% confidence interval of 1685 to 45.39 meters at ( $p < 0.001$ ).

their BNP (brain natriuretic peptide) levels fall from 558 pg/ml to 228 pg/ml after 12 weeks. (*Id.* at LIQ\_PH-ILD\_00000230 (Tbl. 4).) Further, the authors reported a change in FVC % predicted from 62 % at baseline to 63% after 12 weeks. (*Id.* at LIQ\_PH-ILD\_00000228 (Tbl. 2).)

## 6. Faria-Urbina 2018

Faria-Urbina 2018 is a publication titled “Inhaled Treprostинil in Pulmonary Hypertension Associated with Lung Disease” by Mariana Faria-Urbina, Rudolf K.F. Oliveira, Manyoo Agarwal, and Aaron B. Waxman. It was published in 2018 on pages 139-146 in volume 196 of the journal *Lung*. (M. Faria-Urbina, et al., Inhaled Treprostинil in Pulmonary Hypertension Associated with Lung Disease, *Lung* 196:139-146 (2018) (“Faria-Urbina 2018”) (UTC\_PH-ILD\_009936).)

Faria-Urbina 2018 describes a retrospective study in patients with Group 3 PH who were treated with inhaled treprostинil at three breaths (18 µg) four times daily (72 µg) with “doses [] increased as tolerated by three additional breaths (18 µg) per dosing session every 3–7 days to achieve a dose of at least 9–12 breaths or more ( $\geq 54$  µg) four times daily . . . .” (*Id.* at UTC\_PH-ILD\_009937 (Treatment regimen and follow-up).) Nine patients were classified as having ILD, and across all patients the mPAP, PAWP, and PVR were  $44\pm 10$  mmHg,  $10\pm 4$  mmHg, and  $8.1\pm 3.6$  WU respectively. (*Id.* at UTC\_PH-ILD\_009938 (Baseline Characteristics).) Patients were followed for at least three months while on treprostинil. (*Id.* at UTC\_PH-ILD\_009937 (Introduction).)

The authors of Faria-Urbina 2018 report 21 out of the 22 patients in the study “improved (or maintained) functional class[,]” “19 improved SpO<sub>2</sub>; 10 had follow-up with 6MWT—all of them showing improvement in the distance walked.” (*Id.* at UTC\_PH-ILD\_009939.) On the basis of the data, the study concludes that “patients with Group 3 PH treated with [inhaled treprostинil], therapy with [inhaled treprostинil] significantly improved WHO-FC and 6MWT distance” (*id.* (Discussion)) and the results suggest that “iTRE is safe in patients with Group 3 PH and evidence

of pulmonary vascular remodeling in terms of functional class, gas exchange, and exercise capacity” (*id.* at UTC\_PH-ILD\_009936 (Abstract)). The authors concluded that inhaled treprostinil was safe in Group 3 PH patients and showed evidence of improving exercise capacity in those patients. (*Id.* (Abstract, Conclusions).)

In 2018, Dr. Waxman, one of the authors on Faria-Urbina 2018, gave a presentation at UTC’s Science Day on the findings of Faria-Urbina. (A. Waxman, *The iTRE Study: Therapeutic Opportunity for Inhaled Treprostinil in Patients with PH Secondary to Primary Pulmonary Vascular Disease*, UTHR Science Day 2018 (2018) (“Waxman Presentation 2018”) at Slides 11-16 (LIQ\_PH-ILD\_00101301).) In that presentation, which bears UTC’s logo, he noted that 41% of Group 3 PH patients in the study had “ILD,” meaning they had PH-ILD. (*Id.* at Slide 13.) He further reported that patients in the study showed an improvement in 6MWD of +65 m (p = 0.022), meaning the change in the 6-min walk distance was significant. (*Id.* at Slide 13.)

## 7. Parikh 2016

Parikh 2016 is an article titled “Safety and Tolerability of High-dose Inhaled Treprostinil in Pulmonary Hypertension” by Kishan S. Parikh and others that was published on pages 322-325 of Volume 67 Issue 4 of the *Journal of Cardiovascular Pharmacology* in 2016. (K. Parikh., et al., Safety and Tolerability of High-dose Inhaled Treprostinil in Pulmonary Hypertension, *J. Cardiovasc. Pharmacol.* 67(4); 322–25 (2016) (“Parikh 2016”) (UTC\_PH-ILD\_010599).)

Parikh 2016 discloses a retroactive study of 80 PH patients at the Duke University Medical Center PH Clinic. Out of the 80 patients, 25 patients were categorized as having Group 3 PH, 6 of which had pulmonary hypertension associated with interstitial lung disease. (*Id.* at UTC\_PH-ILD\_010607.) The PH clinic protocol put patients on a single administration dosing regimen of 3 breaths (18 mcg)/initial session, 6 breaths (36 mcg)/second session, and then doses were titrated as tolerated, based on side effects, by 1 breath daily until a maximum dosage of 12 breaths (72

- k. Claim 17: “The method of claim 1, wherein said administering increases a 6 minutes walk distance of the patient by at least 10 m after 8 weeks of the administering.”**

For the reasons explained in Asserted Claim 2 above, a POSA would have been motivated to combine the '793 patent, Agarwal 2015, and Saggar 2014 and would have had a reasonable expectation of achieving the limitation recited in Asserted Claim 17 of the '327 patent.

- l. Claim 18: “The method of claim 1, wherein said administering increases a 6 minutes walk distance of the patient by at least 15 m after 12 weeks of the administering.”**

For the reasons explained in Asserted Claim 2 above, a POSA would have been motivated to combine the '793 patent, Agarwal 2015, and Saggar 2014 and would have had a reasonable expectation of achieving the limitation recited in Asserted Claim 18 of the '327 patent.

- m. Claim 19: “The method of claim 1, wherein said administering increases a 6 minutes walk distance of the patient by at least 15 m after 16 weeks of the administering.”**

For the reasons explained in Asserted Claim 2 above, a POSA would have been motivated to combine the '793 patent, Agarwal 2015, and Saggar 2014 and would have had a reasonable expectation of achieving the limitation recited in Asserted Claim 19 of the '327 patent.

**C. Asserted Claims 1–11 and 14–19 of the '327 Patent Are Rendered Obvious by the '793 Patent in Combination with Faria-Urbina 2018 and Saggar 2014**

**1. Motivation to Combine the '793 Patent in Combination with Faria-Urbina 2018 and Saggar 2014 with a Reasonable Expectation of Success.**

A POSA would have been motivated to combine the teachings of the '793 patent with Faria-Urbina 2018 and Saggar 2014 and would have had a reasonable expectation of success in combining these teachings. All three disclose the treatment of PH-ILD with treprostinil. Both the '793 patent and Faria-Urbina 2018 specifically describe treating PH-ILD patients with inhaled treprostinil according to similar dosing schemes (i.e., between 15 and 90 µg in 3 breaths

administered several times per day). (*See* Faria-Urbina 2018 at UTC\_PH-ILD\_009937 (Treatment regimen and follow-up).)

As discussed in Section III.A.3 above, POSAs were already administering inhaled treprostinil to PH-ILD patients and therefore had motivation to combine the teachings of prior art references long before April 2020. At least one of the steering committee members for the INCREASE Study, Dr. Waxman, was motivated to combine the prior art method of treating inhaled treprostinil from the '793 patent with the use of inhaled treprostinil to improve exercise capacity and 6MWD in PH-ILD in Faria-Urbina 2018. (Nathan Dep. Tr. at 206:9-14; 218:10-221:20; 222:25-224:5.) Additionally, the INCREASE Study cites to Faria-Urbina 2018 as motivation for conducting the study. (*See* Waxman 2021 at UTC\_PH-ILD\_010791, UTC\_PH-ILD\_010799.) Furthermore, the co-steering committee members did not doubt that the INCREASE Study would be successful and even UTC's CEO seemed optimistic when asked about the rationale for the INCREASE Study. (*See* Section V.B.1, *supra*, *see also* Nathan Dep. Tr. at 41:12-23, 44:6-11, 159:14-160:25, 202:14-206:7, 222:25-224:5, 232:2-9; UTC 2018 Earnings Call at 10.)

A POSA would have been further motivated to combine Saggar 2014 with the '793 patent and Faria-Urbina 2018 since all three publications describe the use of treprostinil to treat PH, including PH-ILD. Additionally, Faria-Urbina 2018 and Saggar 2014 both disclosed improvements in six-minute walk distance and FVC. While the improvements in Saggar 2014 were due to parenteral treprostinil, a POSA would have been motivated to determine if the benefits in PH-ILD patients treated with parenteral treprostinil would be seen when administering inhaled treprostinil to a patient with PH-ILD instead. Based on the improvements seen in Saggar 2014, a POSA would have had a reasonable expectation of success when combining Saggar 2014 with the '793 patent and Agarwal 2015 to achieve the claimed invention of the '327 patent.

**2. Claim 1 of the '327 Patent Is Obvious Over the '793 Patent in Combination with Faria-Urbina 2018 and Saggar 2014**

- a. Claim 1[a]: “A method of improving exercise capacity in a patient having pulmonary hypertension associated with interstitial lung disease, comprising”**

A POSA would have been motivated to combine the teachings of the '793 patent with Faria-Urbina 2018 and Saggar 2014 to arrive at Asserted Claim limitation 1[a] and would have had a reasonable expectation of success in combining these teachings. For all of the reasons explained in Section IV.A above, the '793 patent discloses a method of treatment for PH, which includes PH-ILD. Additionally, Faria-Urbina 2018 describes a retrospective study in patients with Group 3 PH, including interstitial lung disease, who were treated with inhaled treprostinil. (Faria-Urbina 2018 at UTC\_PH-ILD\_009937 (Treatment regimen and follow-up).) The results of Faria-Urbina 2018 showed “improved (or maintained) functional class[,]” “19 improved SpO<sub>2</sub>; 10 had follow-up with 6MWT—all of them showing improvement in distance walked[.]” (*Id.* at UTC\_PH-ILD\_009939.) On the basis of the data, the study concludes that “patients with Group 3 PH treated with [inhaled treprostinil], therapy with [inhaled treprostinil] significantly improved WHO-FC and 6MWT distance” (*id.* (Discussion)) and “the results suggest that [inhaled treprostinil] is safe in patients with Group 3 PH and evidence of pulmonary vascular remodeling in terms of functional class, gas exchange, and exercise capacity.” (*Id.* at UTC\_PH-ILD\_009936 (Abstract, Conclusions).) Based on the results, the authors concluded that inhaled treprostinil was safe in Group 3 PH patients and showed evidence of improving exercise capacity in those patients. (*Id.*)

A POSA would have been motivated to combine the '793 patent's method of treatment with Faria-Urbina 2018's disclosure of improvements in exercise capacity following treprostinil administration in PH-ILD patients to arrive at Asserted Claim 1[a] which recites “[a] method of improving exercise capacity in a patient having pulmonary hypertension associated with interstitial

lung disease[.]” Because the results in Faria-Urbina 2018 demonstrated suggested improvements in exercise capacity, a POSA would have had a reasonable expectation of success when combining the ’793 patent with Faria-Urbina 2018.

- b. **Claim 1[b]-[d]: “administering by inhalation to the patient having pulmonary hypertension associated with interstitial lung disease an effective amount of at least 15 micrograms up to a maximum tolerated dose of treprostinil or a pharmaceutically acceptable salt thereof in a single administration event that comprises at least 6 micrograms per breath.”**

A POSA would have been motivated to combine the teachings of the ’793 patent with Faria-Urbina 2018 and Saggar 2014 to arrive at Asserted Claim limitations 1[b]-[d] and would have had a reasonable expectation of success in combining these teachings.

As an initial matter, and as explained in Section IV.A.1 above, the ’793 patent discloses Asserted Claim limitations 1[b]-1[d], which recite “administering by inhalation to the patient having pulmonary hypertension associated with interstitial lung disease an effective amount of at least 15 micrograms up to a maximum tolerated dose of treprostinil or a pharmaceutically acceptable salt thereof in a single administration event that comprises at least 6 micrograms per breath.”

A POSA would have been motivated to combine the ’793 patent with Faria-Urbina 2018 since it also discloses these limitations. As described in Section III.B.6 above, Faria-Urbina 2018 discloses the treatment of PH-ILD patients with inhaled treprostinil. Faria-Urbina 2018 also discloses a dosing scheme of three breaths (18 µg) four times daily (72 µg) with “doses [] increased as tolerated by three additional breaths (18 µg) per dosing session every 3–7 days to achieve a dose of at least 9–12 breaths or more ( $\geq 54 \mu\text{g}$ ) four times daily . . . .” (Farina-Urbina 2018 at UTC\_PH-ILD\_009937 (Treatment regimen and follow-up).) Because the publications are in the same field and disclose similar dosing regimens for PH-ILD patients, a POSA would have been motivated to combine the ’793 patent’s method of treatment with the method disclosed in Faria-Urbina 2018’s

to arrive at Asserted Claim limitations 1[b]-[d] and would have had a reasonable expectation of success in doing so.

**3. Dependent Claims 2–11 and 14–19 Are Obvious Over '793 Patent in Combination with Faria-Urbina 2018 and Saggar 2014**

- a. **Claim 2: “The method of claim 1, wherein said administering provides a statistically significant increase of a 6 minutes walk distance in the patient after 8 weeks, 12 weeks, or 16 weeks of the administering.”**

The combination of the '793 patent with Faria-Urbina 2018 and Saggar 2014 make obvious Asserted Claim 2. As described in Section IV.A.2.a above, the '793 patent inherently discloses the limitations of Asserted Claim 2. A POSA would have understood that administering treprostinil as described in the '793 patent would show a statistically significant increase in 6-minute walk distance in a patient after 8 weeks, 12 weeks, or 16 weeks of administering based on the 2017 INCREASE Study Description. (*See* 2017 INCREASE Study Description at 10 (Arms and Interventions; Outcome Measures); Waxman 2021 at UTC\_PH-ILD\_010796 (Figure 2).)

Faria-Urbina 2018 reported that out of the 22 Group 3 PH patients eligible for follow-up analysis, the ten patients that had a follow-up with the six-minute walk test after three months of treatment showed significant improvements in their six-minute walk distances.<sup>23</sup> (Faria-Urbina 2018 at UTC\_PH-ILD\_009938, UTC\_PH-ILD\_009940). Table 2 shows that the average increase in 6MWD was 65 meters (reporting a baseline of  $243 \pm 106$  meters, a follow-up score of  $309 \pm 109$  meters, and a p value of 0.022). (*Id.* UTC\_PH-ILD\_009940 (Table 2).)

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<sup>23</sup> Note that on UTC\_PH-ILD\_009939, the authors write that only “10 had follow-up with 6MWT— all of them showing improvement in the distance walked[.]” However, the authors report that there were 11 patients who took the 6MWT at the follow-up on UTC\_PH-ILD\_009938, in Table 2 on UTC\_PH-ILD\_009940, and in Fig. 3 on UTC\_PH-ILD\_009940. To err on the conservative side, Liquidia has chosen to assume that at least 10 patients took the follow-up 6MWT for the purposes of these invalidity contentions.

Saggar 2014 also discloses a statistically significant improvement in 6-minute walk distance after 12 weeks. Table 2 of Saggar 2014 shows that there was a mean improvement of 59 meters in patients' 6-minute walk distance after 12 weeks of treprostinil therapy ( $p<0.001$ ). (Saggar 2014 at LIQ\_PH-ILD\_00000228-229.) A POSA would have been motivated to combine Faria-Urbina 2018 and Saggar 2014 with the '793 patent since all three prior art references describe the use of treprostinil to treat PH, including PH-ILD, and show an improvement in 6MWD to arrive at the limitation recited in Asserted Claim 2 of the '327 patent and would have had a reasonable expectation of success in doing so.

**b. Claim 3: “The method of claim 1, wherein said administering increases a 6 minutes walk distance of the patient by at least 10 m after 8 weeks, 12 weeks, or 16 weeks of the administering.”**

Based on the reasons explained for Asserted Claim 2 above, a POSA would have been motivated to combine the '793 patent, Faria-Urbina 2018, and Saggar 2014 and would have a reasonable expectation of success in achieving the limitation in Asserted Claim 3 of the '327 patent.

**c. Claims 4 and 5: “The method of claim 1, wherein said administering provides a statistically significant reduction of a plasma concentration of NT-proBNP in the patient after 8 weeks, 12 weeks, or 16 weeks of the administering[]” and “[t]he method of claim 1, wherein said administering reduces a plasma concentration of NT-proBNP in the patient by at least 200 pg/ml after 8 weeks, 12 weeks, or 16 weeks of the administering.”**

A POSA would have been motivated to combine the teachings of the '793 patent with Faria-Urbina 2018 and Saggar 2014 to arrive at the limitations in Asserted Claims 4 and 5 and would have had a reasonable expectation of success in combining these teachings. As explained above in Section IV.A.2.c, the '793 patent inherently discloses Asserted Claim 4 because it uses the same dosing regimen employed in the INCREASE Study (both describe  $> 15 \mu\text{g}$  including 54  $\mu\text{g}$ , in multiple breaths including 9 breaths, more than one time per day with 6  $\mu\text{g}$  per breath) where

NT-proBNP levels dropped 203.4 pg/ml by 8 weeks into the study. (See Section III.B.1, *supra*; Waxman 2021 at UTC\_PH-ILD\_010792, UTC\_PH-ILD\_010816 (Figure S4).) The '793 patent also reports a reduction of at least 200 pg/ml after 8 weeks as described in Section IV.A.2.d, above.

In Saggar 2014, patients treated with parenteral treprostinil saw their BNP (brain natriuretic peptide) levels fall from 558 pg/ml to 228 pg/ml, a difference of 330 pg/ml, after 12 weeks, which would give a POSA a reasonable expectation of success in seeing a reduction of at least 200 pg/ml after at least 8 weeks when administering inhaled treprostinil. (Saggar 2014 at LIQ\_PH-ILD\_00000230 (Tbl. 4).) Because BNP and NT-proBNP are both good indicators of disease severity in PH, there is a positive correlation between the two biomarkers, and there is no clear advantage in using one biomarker over the other, a POSA would have understood that Saggar 2014's statistically significant reduction of BNP levels is equivalent to a statistically significant reduction in NT-proBNP levels.<sup>24</sup> A POSA would understand the positive correlation between the two biomarkers and would be motivated to combine Saggar 2014 with Parikh 2016 with the '793 patent to achieve Asserted Claim 4 and would have had a reasonable expectation of success in doing so.

A POSA would be motived to combine the teachings of Faria-Urbina 2018 with the '793 patent and Saggar 2014 to determine the effects of inhaled treprostinil on NT-proBNP since all three publications describe improvements in 6MWD and hemodynamic parameters as a result of using treprostinil to treat PH, including PH-ILD. By combining Saggar 2014 with Faria-Urbina 2018 and the '793 patent, a POSA would have expected patients treated with inhaled treprostinil

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<sup>24</sup> See Robert P. Frantz et al, *Baseline NT-proBNP correlates with change in 6-minute walk distance in patients with pulmonary arterial hypertension in the pivotal inhaled treprostinil study TRIUMPH-1*, 31 J. Heart & Lung Transplantation 811, 812 (2012) (available at [https://www.jhltonline.org/article/S1053-2498\(12\)01076-5/fulltext](https://www.jhltonline.org/article/S1053-2498(12)01076-5/fulltext)) (LIQ\_PH-ILD\_00101518).

to show a similar reduction in their NT-proBNP (brain natriuretic peptide) levels. Thus, Asserted Claims 4 and 5 of the '327 patent are invalid as obvious.

**d. Claim 6: “The method of claim 1, wherein said administering provides a statistically significant reduction of at least one exacerbations of the interstitial lung disease.”**

The '793 patent in combination with Faria-Urbina 2018 and Saggar 2014 discloses Asserted Claim 6. As explained above in Section IV.A.2.e, the '793 patent discloses “wherein said administering provides a statistically significant reduction of at least one exacerbations of the interstitial lung disease.”

Faria-Urbina 2018 further discloses an improvement in exacerbations. It discloses that 21 out of the 22 patients in the study “improved (or maintained) functional class[,]” “19 improved SpO<sub>2</sub>; 10 had follow-up with 6MWT—all of them showing improvement in distance walked[.]” (Faria-Urbina 2018 at UTC\_PH-ILD\_009939.) On the basis of the data, the study concludes that “patients with Group 3 PH treated with [inhaled treprostинil], therapy with [inhaled treprostинil] significantly improved WHO-FC and 6MWT distance.” (*Id.* (Discussion).) and “the results suggest that “[inhaled treprostинil] is safe in patients with Group 3 PH and evidence of pulmonary vascular remodeling in terms of functional class, gas exchange, and exercise capacity.” (*Id.* at UTC\_PH-ILD\_009936 (Abstract, Conclusions).) Because Faria-Urbina 2018 describes an overall benefit to the patients, a POSA would have expected that the patients also showed an improvement in PH-ILD exacerbations. A POSA would have also understood that exacerbations are associated with deterioration in functional capacity, while in contrast, Faria-Urbina 2018 reports that patients had improvements on these parameters.

Saggar 2014 disclosed improvements in FVC and 6MWD, along with dyspnea and quality of life which were measured using the University of California San Diego Shortness of Breath (UCSD SOB) questionnaire and Short Form Health Survey respectively. (Saggar 2014 at

LIQ\_PH-ILD\_00000228-229.) The authors reported a statistically significant improvement in each of these metrics. In particular, patients responding to questions in the Short Form Health Survey reported improvements in their physical functioning, bodily pain, general health, and vitality. (Saggar 2014 at LIQ\_PH-ILD\_00000229.) Because Saggar 2014 describes an overall benefit to patients, and in particular describes improvements in functional capacity, including patients self-reported improvements in physical health, a POSA would have understood that the patients likely had improvements in PH-ILD exacerbations.

A POSA would have been motivated to combine the '793 patent with Faria-Urbina 2018 and Saggar 2014 since all three publications describe the use of treprostinil to treat PH, including PH-ILD, and show improvements in functional capacity, which inversely correlates with exacerbations. By combining the disclosures of these three references, a POSA would have had a reasonable expectation of success in achieving the limitation of Asserted Claim 6 of the '327 patent.

- e. **Claims 7 and 8:** “The method of claim 1, wherein said administering provides a statistically significant reduction of clinical worsening events due to the interstitial lung disease[]” and “[t]he method of claim 7, wherein the clinical worsening events comprise at least one of hospitalization for cardiopulmonary indication and a decrease in a 6-minute walk distance by more than 15% compared a baseline 6-minute walk distance prior to the administering.”

The '793 patent in combination with Faria-Urbina 2018 and Saggar 2014 discloses Asserted Claims 7 and 8. Sections IV.A.2.f and IV.A.2.g above discusses how the '793 patent discloses “a statistically significant reduction of clinical worsening events due to the interstitial lung disease” and “wherein the clinical worsening events comprise at least one of hospitalization for cardiopulmonary indication and a decrease in a 6-minute walk distance by more than 15% compared a baseline 6-minute walk distance prior to the administering.” For those same reasons, the '793 patent in combination with Faria-Urbina 2018 and Saggar 2014 discloses Asserted Claims

7 and 8. Moreover, because the results in Faria-Urbina 2018 and Saggar 2014 show improvements that inversely relate to clinical worsening events (notably an increase in six-minute walk distance rather than a decrease) a POSA would expect to have reasonable success in seeing a statistically significant reduction in clinical worsening events when treating a patient with PH-ILD using the dosing regimens in Faria-Urbina 2018 and Saggar 2014. Accordingly, Asserted Claims 7 and 8 are invalid as obvious.

- f. **Claims 9 and 10:** “**The method of claim 1, wherein said administering provides a statistically significant improves of forced vital capacity (FVC) in the patient after 8 weeks, 12 weeks, or 16 weeks of the administering[]” and “[t]he method of claim 9, wherein said administering improves the forced vital capacity (FVC) in the patient by at least 20 ml after 8 weeks, 12 weeks, or 16 weeks of the administering.”**

Asserted Claim 9 requires that “said administering provides a statistically significant improves [sic] of forced vital capacity (FVC) in the patient after 8 weeks, 12 weeks, or 16 weeks of the administering.” Claim 10 requires that “said administering improves the forced vital capacity (FVC) in the patient by at least 20 ml after 8 weeks, 12 weeks, or 16 weeks of the administering.” A POSA would have been motivated to combine the teachings of the ’793 patent with Faria-Urbina 2018 and Saggar 2014 to arrive at Asserted Claims 9 and 10 and would have had a reasonable expectation of success in combining these teachings.

As explained in Sections IV.A.2.h and IV.A.2.i above, the ’793 patent discloses Asserted Claims 9 and 10. Further, the ’793 patent in combination with Faria-Urbina 2018 and Saggar 2014 discloses these claims. With respect to the improvement in FVC, 20 mL of lung volume is approximately 1–2 % of lung volume. While not statistically significant, Faria-Urbina 2018 does disclose an improvement of 8% in FVC % predicted after a period of three months (change from  $67\pm26$  baseline to  $59\pm22$  follow-up with a p value of 0.12) which at the very least discloses FVC as a metric for evaluating the effects of inhaled treprostinil in PH-ILD patients. (Faria-Urbina

2018 at UTC\_PH-ILD\_009940.)

On the other hand, Saggar 2014 discloses a 1% improvement in FVC predicted %. (Saggar 2014 at LIQ\_PH-ILD\_00000228 (Tbl. 2).) This 1% change is comparable to the 1.1% change described in the INCREASE Study which the INCREASE Study reports as a significant improvement in FVC. (Waxman 2021 at UTC\_PH-ILD\_010825 (Tbl. S6).) Thus, to the extent the INCREASE Study and the '327 patent report that a 1.1% effect is significant, so too is the improvement reported in Saggar 2014.

A POSA would have been motivated to combine Saggar 2014 with the '793 patent and Faria-Urbina 2018 since all of these publications describe the use of treprostinil to treat PH, including PH-ILD. Moreover, a POSA would have had a reasonable expectation of success in achieving Asserted Claims 9 and 10 of the '327 patent given the improvement reported in Saggar 2014.

**g. Claims 11 and 14:** “**The method of claim 1, wherein said administering is performed by a pulsed inhalation device[]” and “[t]he method of claim 11, wherein the pulsed inhalation device is a dry powder inhaler comprising a dry powder comprising treprostinil or a pharmaceutically acceptable salt thereof.”**

Asserted Claims 11 and 14 are disclosed by the combination of the '793 patent, Faria-Urbina 2018, and Saggar 2014. Sections IV.A.2.j and IV.A.2.k above discusses how the '793 patent discloses “administering is performed by a pulsed inhalation device” and “the pulsed inhalation device is a dry powder inhaler comprising a dry powder comprising treprostinil or a pharmaceutically acceptable salt thereof.” For those same reasons, the '793 patent in combination with Faria-Urbina 2018 discloses Asserted Claims 11 and 14. Moreover, because dry powder inhalers are smaller and more convenient than nebulizers, a POSA would have been motivated to apply the dry powder inhaler of the '793 patent to the teachings of Faria-Urbina 2018 and Saggar 2014 and would have had a reasonable expectation of success in doing so to achieve Asserted

Claims 11 and 14 of the '327 patent.

- h. **Claim 15: “The method of claim 1, wherein the effective amount of treprostinil or a pharmaceutically acceptable salt administered to the patient in a single inhalation administration event is from 15 µg to 100 µg.”**

A POSA would have been motivated to combine the teachings of the '793 patent with Faria-Urbina 2018 and Saggar 2014 to arrive at Asserted Claim 15 and would have had a reasonable expectation of success in combining these teachings.

Claim 15 is disclosed by the combination of the '793 patent, Faria-Urbina 2018, and Saggar 2014. As explained in section IV.A.2.1 above, the '793 patent discloses Asserted Claim 15. A POSA would understand that a “single event dose” is equivalent to a “single inhalation administration event” because both phrases refer to a single instance of administering inhaled treprostinil. From the specification, a POSA would have understood that 15 µg to about 100 µg in preferably 3, 2, or 1 breaths would be anywhere from 5 µg to 100 µg per breath (i.e., 15 µg/3 breaths to 100 µg/1 breath), which discloses Asserted Claim 15. (*See also* '793 patent at UTC\_PH-ILD\_009791 (7:55-59; 7:60-64).)

Furthermore, Faria-Urbina 2018 discloses a dosing regimen of three breaths (18 µg) four times daily (72 µg) with “doses [] increased as tolerated by three additional breaths (18 µg) per dosing session every 3–7 days to achieve a dose of at least 9–12 breaths or more ( $\geq 54 \mu\text{g}$ ) four times daily . . . .” (Faria-Urbina 2018 at UTC\_PH-ILD\_009937 (Treatment regimen and follow-up).) Based on the state of the art in 2018 (including the Tyvaso® Label and the fact that physicians regularly dosed patients with 3-breaths 4x daily to a goal of 9-12 breaths as tolerated), a POSA would have expected that three breaths four times daily refers to the known dosing regimen for Tyvaso®, which in 2018 started at 3 breaths 4 times daily with approximately 6 µg of treprostinil per breath. Therefore Faria-Urbina 2018 discloses an effective amount of treprostinil or a pharmaceutically acceptable salt in the amount of 18-72 µg.

Because the '793 patent and Faria-Urbina 2018 describe the use of treprostinil to treat PH, including PH-ILD, a POSA would have been motivated to combine them to achieve the limitations of Asserted Claim 15 of the '327 patent and would have a reasonable expectation of success in doing so.

i. **Claim 16: “The method of claim 15, wherein the single inhalation administration event does not exceed 15 breaths by the patient.”**

The '793 patent in combination with Faria-Urbina 2018 discloses Asserted Claim 16. The '793 patent discloses that administering treprostinil in a single event can occur “in 20 breaths or less, or in 10 breaths or less, or than 5 breaths or less” thereby anticipating Asserted Claim 16. ('793 patent at UTC\_PH-ILD\_009791 (7:60-64).) It further discloses that treprostinil is preferably administer in 3, 2, or 1 breaths, which do not exceed the 15 breaths limitation covered by Asserted Claim 16. (*Id.*)

Faria-Urbina 2018 discloses administering a maximum of 12 breaths per single inhalation administration event. (Faria-Urbina 2018 at UTC\_PH-ILD\_009937 (Treatment regimen and follow-up).) While it suggests that a patient could be administered more than 12 breaths, it does not disclose any patient being treated with a higher dosage than 12 breaths per single administration event. (*Id.*)

A POSA would have been motivated to combine the '793 patent and Faria-Urbina 2018 to achieve the disclosure of Asserted Claim 16 and would have a reasonable expectation of success because they both describe the use of treprostinil to treat PH, including PH-ILD as well as similar dosing regimens.

- j. **Claim 17: “The method of claim 1, wherein said administering increases a 6 minutes walk distance of the patient by at least 10 m after 8 weeks of the administering.”**

Based on the reasons explained for Asserted Claim 2 above, a POSA would have been motivated to combine the '793 patent, Faria-Urbina 2018, and Saggar 2014 and would have a reasonable expectation of success in achieving the limitation in Asserted Claim 17 of the '327 patent.

- k. **Claim 18: “The method of claim 1, wherein said administering increases a 6 minutes walk distance of the patient by at least 15 m after 12 weeks of the administering.”**

Based on the reasons explained for Asserted Claim 2 above, a POSA would have been motivated to combine the '793 patent, Faria-Urbina 2018, and Saggar 2014 and would have a reasonable expectation of success in achieving the limitation in Asserted Claim 18 of the '327 patent.

- l. **Claim 19: “The method of claim 1, wherein said administering increases a 6 minutes walk distance of the patient by at least 15 m after 16 weeks of the administering.”**

Based on the reasons explained for Asserted Claim 2 above, a POSA would have been motivated to combine the '793 patent, Faria-Urbina 2018, and Saggar 2014 and would have a reasonable expectation of success in achieving the limitation in Asserted Claim 19 of the '327 patent.

**D. Asserted Claims 1–11 and 14–19 of the '327 Patent Are Rendered Obvious by the '793 Patent in Combination with Parikh 2016 and Saggar 2014**

**1. Motivation to Combine the '793 Patent in Combination with Parikh 2016 and Saggar 2014 with a Reasonable Expectation of Success.**

A POSA would have been motivated to combine the teachings of the '793 patent with Parikh 2016 and Saggar 2014 and would have had a reasonable expectation of success in combining these teachings. As an initial matter, a POSA would have been motivated to combine

- n. **Claim 19: “The method of claim 1, wherein said administering increases a 6 minutes walk distance of the patient by at least 15 m after 16 weeks of the administering.”**

For the same reasons explained for Asserted Claim 2 above, a POSA would have been motivated to combine Agarwal 2015 and Saggar 2014 and would have a reasonable expectation of success in achieving the limitation in Asserted Claim 19 of the ’327 patent. Thus, these references render Asserted Claim 19 of the ’327 patent obvious.

**F. Asserted Claims 1–11 and 15–19 of the ’327 Patent Are Rendered Obvious by the 2017 INCREASE Study Description in Combination with Agarwal 2015 and Saggar 2014**

**1. Motivation to combine**

To the extent UTC contends Agarwal 2015 and Saggar 2014 do not render the Asserted Claims obvious, the Asserted Claims are obvious over the 2017 INCREASE Study Description in combination with Agarwal 2015 and Saggar 2014. A POSA would have been motivated to combine the 2017 INCREASE Study Description with Agarwal 2015 and Saggar 2014 and would have had a reasonable expectation of success in combining these teachings. All three references belong to the same field in that they disclose treprostinil therapy for patients with Group 3 PH with PH-ILD. As explained by Dr. Channick, and as shown by the 2017 INCREASE Study Description and Agarwal 2015, POSAs were administering inhaled treprostinil to PH-ILD patients prior to April 2020. (Channick Decl., ¶¶41–52.) Physicians were also measuring hemodynamics in these patients and also saw significant improvements in exercise capacity. Thus, POSAs were motivated to, and were in practice, combining the teachings of prior art references before April 2020.

Dr. Waxman was a principal investigator in the INCREASE Study and was also an author of Agarwal 2015. (See 2017 INCREASE Study Description at LIQ\_PH-ILD\_00000198; Agarwal 2015 at UTC\_PH-ILD\_009828.) Thus, he would have been aware of the successful treatment of PH-ILD using inhaled treprostinil and the associated improvement in 6MWD which translates to

an improvement in exercise capacity. Dr. Waxman would have also been aware that the INCREASE Study and Agarwal 2015 used highly similar dosing regimens for inhaled treprostinil. Indeed, the INCREASE Study cites to Agarwal 2015 as a motivation for conducting the study, stating:

Data from previously completed pilot studies suggest that inhaled treprostinil can improve hemodynamics and functional capacity in patients with group 3 pulmonary hypertension. Therefore, the objective of the INCREASE trial was to evaluate the safety and efficacy of inhaled treprostinil in patients with [PH-ILD].

(Waxman 2021 at UTC\_PH-ILD\_010791, UTC\_PH-ILD\_010799 (citing Agarwal 2015 among other studies).) Thus, a POSA would have been motivated to combine the 2017 INCREASE Study Description with Agarwal 2015 and have a reasonable expectation of success. In fact, Dr. Nathan himself stated that, in 2019, he was “cautiously optimistic” that the INCREASE study would demonstrate positive results. (PFF Summit 2019 at 15:56.) And long before the April 2020 critical date, UTC was publicly acknowledging that PH-ILD patients benefitted from inhaled treprostinil.

UTC’s CEO, Dr. Martine Rothblatt, told investors in 2018 that:

[B]oth through the effort of our medical affairs group over the years in supporting investigator-sponsored studies and through the kindness and generosity of certain payers around the country who have gone ahead and upon the initiative of their physicians, *were able to enable some WHO Group III patients to benefit* [from Tyvaso and], there were unmistakable signals from some of the leading physicians in the field. I called out one of them on the call, Dr. Waxman, but there are many others, who said to UT, “*This drug works.*” In fact, they believe that this drug works even better in that indication than in the Group I indication, in terms of, at least, the exercise ability that they saw in their patients, discounting any placebo effects that might be involved.

(UTC 2018 Earnings Call at 10 (emphasis added).)

For the same reasons explained above in Section V.B.1, previous clinical studies with other drugs and in other patient populations would not have discouraged a POSA from using a Group 1 PAH therapy like inhaled treprostinil in a patient with PH-ILD.

A POSA would have been further motivated to combine Saggar 2014 with the 2017 INCREASE Study Description and Agarwal 2015. All three references describe the use of treprostinil to treat PH, including PH-ILD and measure 6MWD, with Saggar 2014 also measuring NT-BNP levels and FVC. Patients in Saggar 2014 saw improvements in their six-minute walk distance, as well as reductions in their BNP levels. (Saggar 2014 at LIQ\_PH-ILD\_00000229, LIQ\_PH-ILD\_00000230 (Tbl. 4).) Further, the authors reported a change in FVC % predicted from 62% at baseline to 63% after 12 weeks. (*Id.* at LIQ\_PH-ILD\_00000228 (Tbl. 2).) While the improvements in Saggar 2014 were due to parenteral treprostinil, a POSA would have been motivated to determine if the BNP and FVC benefits in PH-ILD patients treated with parenteral treprostinil could also be seen with inhaled treprostinil. A POSA would have had a reasonable expectation of success given the promising improvements seen in Saggar 2014.

**2. Claim 1 of the '327 Patent Is Obvious Over the 2017 INCREASE Study Description in Combination with Agarwal 2015 and Saggar 2014**

**a. Claim 1[a]: “A method of improving exercise capacity in a patient having pulmonary hypertension associated with interstitial lung disease, comprising”**

The 2017 INCREASE Study Description discloses measuring “[c]hange[s] in 6-minute Walk Distance (6MWD) Measured at Peak Exposure from Baseline to Week 16” by administering “active inhaled treprostinil” “via an ultrasonic nebulizer” to “subjects with pre-capillary pulmonary hypertension (PH) associated with interstitial lung disease (ILD).” (2017 INCREASE Study Description at 9–11.) As explained above in Section IV.B.1, new uses for a known compound are deemed inherent even when the use and method are disclosed but the results are published after the priority date. Accordingly, the 2017 INCREASE Study Description discloses Asserted Claim limitation 1[a] of the '327 patent even though it does not explicitly report on improvements in exercise capacity.

For the same reasons discussed above in Section V.E.2.a, the combination of Agarwal 2015, and Saggar 2014 discloses the elements of Asserted Claim limitation 1[a] of the '327 patent. Because all three references describe the use of treprostinil to treat PH, including PH-ILD, and all three measure 6MWD, among other metrics, a POSA would have a reasonable expectation of success in combining the references to develop a method of improving exercise capacity in patients with PH-ILD.

- b. **Claim 1[b]-[d]: “administering by inhalation to the patient having pulmonary hypertension associated with interstitial lung disease an effective amount of at least 15 micrograms up to a maximum tolerated dose of treprostinil or a pharmaceutically acceptable salt thereof in a single administration event that comprises at least 6 micrograms per breath.”**

The 2017 INCREASE Study Description discloses Asserted Claim limitations 1[b]-[d] because it teaches administering “active inhaled treprostinil” in doses of “approximately 6 mcg per breath” and “[i]nhaled four times daily and titrated up to a maximum of 12 breaths four times daily.” (2017 INCREASE Study Description at 9–11.) A POSA would have understood that “12 breaths four times daily” of “6 mcg per breath” is equivalent to 72 µg, which exceeds the at least 15 micrograms in a single administration event as required by Asserted Claim limitations 1[b]-[d] of the '327 patent.

For the same reasons discussed above in Section V.E.2.b, Agarwal 2015 discloses the elements of Asserted Claim limitations 1[b]-[d] of the '327 patent.

**3. Dependent Claims 2–11 and 15–19 Are Rendered Obvious by the 2017 INCREASE Study Description in Combination with Agarwal 2015 and Saggar 2014**

- a. **Claim 2: “The method of claim 1, wherein said administering provides a statistically significant increase of a 6 minutes walk distance in the patient after 8 weeks, 12 weeks, or 16 weeks of the administering.”**

The 2017 INCREASE Study Description discloses claim 2. The 2017 INCREASE Study Description discloses measuring 6MWD at baseline and at week 16 as a primary outcome measure:

1. Change in 6-minute Walk Distance (6MWD) Measured at Peak Exposure from Baseline to Week 16

The intent of the 6MWD test is to evaluate exercise capacity associated with carrying out activities of daily living. Change in 6MWD from Baseline to Week 16, correlates with the current clinical standard for assessing patient functional status in the treatment of PH and is considered an objective measure of patient functional status. Subjects will be instructed to walk down a corridor at a comfortable speed as far as they can manage for six minutes. Distance <500 meters suggests considerable exercise limitation; Distance 500-800 meters suggests moderate limitation; Distance >800 meters (with no rests) suggests mild or no limitation. Peak exposure 6MWD will occur by conducting 6-minute walk test (6MWT) within 10 to 60 minutes after the most recent dose of study drug dose.

[Time Frame: Baseline and Week 16]

(2017 INCREASE Study Description at 10 (Primary Outcome Measures).) The 2017 INCREASE Study Description inherently discloses Asserted Claim 2 in that it prescribes the same dose, dosing regimen, patient population, and end points measured in the actual INCREASE Study. The INCREASE Study reported a change of 31.12 meters from baseline in 6MWD over the 16 weeks ( $p<0.001$ ). (Waxman 2021 at UTC\_PH-ILD\_010793.) The study also discloses at least a 10 meter improvement at week 8, at least a 15 meter improvement at week 12, and at least a 20 meter improvement at week 16. (*Id.* at UTC\_PH-ILD\_010796 (Figure 2).) Thus, administering inhaled treprostinil per the 2017 INCREASE Study Description necessarily and inevitably discloses Asserted Claim 2 of the '327 patent.

For the same reasons discussed above in Section V.E.3.a, Agarwal 2015 and Saggar 2014 disclose the elements of Asserted Claim 2 of the '327 patent. Thus, these references render Asserted Claim 2 of the '327 patent obvious.

- a. **Claim 3: “The method of claim 1, wherein said administering increases a 6 minutes walk distance of the patient by at least 10 m after 8 weeks, 12 weeks, or 16 weeks of the administering.”**

For the same reasons discussed above in Asserted Claim 2, the 2017 INCREASE Study Description discloses the elements of Asserted Claim 3 of the '327 patent.

For the same reasons discussed above in Section V.E.3.b, Agarwal 2015 and Saggar 2014 disclose the elements of Asserted Claim 3 of the '327 patent.

Thus, these references render Asserted Claim 3 of the '327 patent obvious.

- b. **Claim 4: “The method of claim 1, wherein said administering provides a statistically significant reduction of a plasma concentration of NT-proBNP in the patient after 8 weeks, 12 weeks, or 16 weeks of the administering.”**

The 2017 INCREASE Study Description discloses Asserted Claim 4. The 2017 INCREASE Study Description teaches measuring the “[c]hange in plasma concentration of N-terminal pro-Brain Natriuretic Peptide (NT-proBNP) from Baseline to Week 16[.]”

3. Change in plasma concentration of N-terminal pro-Brain Natriuretic Peptide (NT-proBNP) from Baseline to Week 16

The N-terminal pro-BNP (NT-proBNP) serum concentration is a useful biomarker associated with changes in right heart morphology and function. NT-proBNP serum concentration will be assessed to compare the severity of heart failure at Baseline and Week 16. Blood for NT-proBNP assessment must be drawn prior to conducting the 6-minute walk test (6MWT).

[Time Frame: Baseline and Week 16]

(2017 INCREASE Study Description at 11 (Secondary Outcome Measures).) The 2017 INCREASE Study Description inherently discloses Asserted Claim 4 because it embodies the same dose, dosing regimen, patient population, and end points measured in the actual INCREASE Study. The INCREASE Study reports a decrease of 15% in the plasma concentration of NT-

proBNP over 16 weeks. (Waxman 2021 at UTC\_PH-ILD\_010790 (results).) By 8 weeks, NT-proBNP levels had dropped from 2118.75 pg/ml to 1915.35 pg/ml, a drop of 203.4 pg/ml. (*Id.* at UTC\_PH-ILD\_010816 (Figure S4).) Thus, administering treprostinil according to the teachings of the 2017 INCREASE Study Description necessarily and inevitably discloses Asserted Claim 4 of the '327 patent.

For the same reasons discussed above in Section V.E.3.c, Agarwal 2015 and Saggar 2014 disclose the elements of Asserted Claim 4 of the '327 patent. Thus, these references render Asserted Claim 4 of the '327 patent obvious.

**c.      *Claim 5: “The method of claim 1, wherein said administering reduces a plasma concentration of NT-proBNP in the patient by at least 200 pg/ml after 8 weeks, 12 weeks, or 16 weeks of the administering.”***

For the same reasons discussed above in Asserted Claim 4, the 2017 INCREASE Study Description discloses the elements of Asserted Claim 5 of the '327 patent.

For the same reasons discussed above in Section V.E.3.d, Agarwal 2015 and Saggar 2014 disclose the elements of Asserted Claim 5 of the '327 patent.

Thus, these references render Asserted Claim 5 of the '327 patent obvious.

**d.      *Claim 6: “The method of claim 1, wherein said administering provides a statistically significant reduction of at least one exacerbations of the interstitial lung disease.”***

The 2017 INCREASE Study Description inherently discloses claim 6. The 2017 INCREASE Study Description teaches a POSA to measure adverse events among participants through 16 weeks. (2017 INCREASE Study Description at 9–11.) A POSA would have understood that measuring adverse events would include measuring exacerbations of the lung disease. Because the 2017 INCREASE Study Description is the description of the protocol for the INCREASE Study, it thus recites the same dose, dosing regimen, patient population, and end points measured in the actual INCREASE Study. The INCREASE Study reports a statistically

significant reduction of at least one exacerbation of interstitial lung disease. (*See also* Waxman 2021 at UTC\_PH-ILD\_010796, UTC\_PH-ILD\_010798.) Thus, administering treprostinil according to the teachings of the 2017 INCREASE Study Description necessarily and inevitably discloses Asserted Claim 6 of the '327 patent.

For the same reasons discussed above in Section V.E.3.e, Agarwal 2015 and Saggar 2014 disclose the elements of Asserted Claim 6 of the '327 patent.

Thus, these references render Asserted Claim 6 of the '327 patent obvious. Because all three references describe the use of treprostinil to treat PH, including PH-ILD, and all three measure 6MWD, among other metrics, a POSA would have a reasonable expectation of success in combining the references to achieve the limitations of Asserted Claim 6 of the '327 patent.

e. **Claim 7: “The method of claim 1, wherein said administering provides a statistically significant reduction of clinical worsening events due to the interstitial lung disease.”**

The 2017 INCREASE Study Description inherently discloses Asserted Claim 7. The 2017 INCREASE Study Description recites the same dose, dosing regimen, patient population, and end points measured in the actual INCREASE Study. Although clinical worsening events are not explicitly disclosed in the 2017 INCREASE Study Description, as noted above in Section IV.B.2.f, the INCREASE Study concluded that “treatment with inhaled treprostinil was associated with a lower risk of clinical worsening” (clinical worsening occurred in 22.7% of the treprostinil group compared to 33.1% in the placebo group). (Waxman 2021 at UTC\_PH-ILD\_010794, UTC\_PH-ILD\_010798.) Because the dosing regimen in the INCREASE Study was already disclosed in the 2017 INCREASE Study Description, a POSA would have understood that administering treprostinil as described in the 2017 INCREASE Study Description would have necessarily and inevitably resulted in a statistically significant reduction of clinical worsening events due to interstitial lung disease, even though the study results may have been published after the critical

date. As such, the 2017 INCREASE Study Description inherently discloses Asserted Claim 7 of the '327 patent.

For the same reasons discussed above in Section V.E.3.f, Agarwal 2015 and Saggar 2014 disclose the elements of Asserted Claim 7 of the '327 patent.

Thus, these references render Asserted Claim 7 of the '327 patent obvious.

**f.      Claim 8: “The method of claim 7, wherein the clinical worsening events comprise at least one of hospitalization for cardiopulmonary indication and a decrease in a 6-minute walk distance by more than 15% compared a baseline 6-minute walk distance prior to the administering.”**

The 2017 INCREASE Study Description inherently discloses Asserted Claim 8. The 2017 INCREASE Study Description is the description of the protocol for the INCREASE Study, and thus recites the same dose, dosing regimen, patient population, and end points measured in the INCREASE Study. As described in Section III.A.4, the INCREASE Study evaluated the time to clinical worsening events “from the time of randomization until the patient’s withdrawal from the trial and [defined it] as the time until the occurrence of any one of the following events: hospitalization for a cardiopulmonary indication, a decrease in 6-minute walk distance greater than 15% from baseline that was directly related to the disease . . . death from any cause, or lung transplantation.” (Waxman 2021 at UTC\_PH-ILD\_010792.) The INCREASE Study confirmed that treatment with inhaled treprostinil reduced such clinical worsening events. (*Id.* at UTC\_PH-ILD\_010794, UTC\_PH-ILD\_010798.) Therefore, administering treprostinil according to the teachings of the 2017 INCREASE Study Description necessarily and inevitably discloses Asserted Claim 8 of the '327 patent.

For the same reasons discussed above for Section V.E.3.g, Agarwal 2015 and Saggar 2014 disclose the elements of Asserted Claim 8 of the '327 patent.

Thus, these references render Asserted Claim 8 of the '327 patent obvious.

- g. Claim 9: "The method of claim 1, wherein said administering provides a statistically significant improvement of forced vital capacity (FVC) in the patient after 8 weeks, 12 weeks or 16 weeks of the administering."**

The 2017 INCREASE Study Description also discloses Asserted Claim 9. The 2017 INCREASE Study Description discloses measuring changes in forced vital capacity from baseline to Week 16 as a secondary outcome measure:

5. Change in Forced Vital Capacity (FVC) from Baseline to Week 16  
Change in pulmonary function following inhaled treprostinil therapy will be measured by Forced Vital Capacity (FVC), calculated from a Pulmonary Function Test (PFT) performed at Baseline and Week 16.  
[Time Frame: Baseline and Week 16]

(2017 INCREASE Study Description at 11 (Secondary Outcome Measures).) The 2017 INCREASE Study Description inherently discloses Asserted Claim 9. This is because the 2017 INCREASE Study Description is the description of the protocol for the INCREASE Study, and thus recites the same dose, dosing regimen, patient population, and end points measured in the INCREASE Study. As noted above in Section III.A.4, the INCREASE Study reports a statistically significant improvement of FVC % predicted after 16 weeks of administering treprostinil to patients with PH-ILD. (See Waxman 2021 at UTC\_PH-ILD\_010825 (Table S6).) Thus, administering treprostinil according to the teachings of the 2017 INCREASE Study Description discloses Asserted Claim 9 of the '327 patent.

Thus, these references render Asserted Claim 9 of the '327 patent obvious.

- h. Claim 10: "The method of claim 9, wherein said administering improves the forced vital capacity (FVC) in the patient by at least 20 ml after 8 weeks, 12 weeks, or 16 weeks of the administering"**

As explained above for Asserted Claim 9, the 2017 INCREASE Study Description teaches a POSA to measure FVC from baseline to 16 weeks in PH-ILD patients administered treprostinil.

For the same reasons as discussed above for Asserted Claim 9, the 2017 INCREASE Study Description inherently discloses Asserted Claim 10. As noted above in Section IV.A.2.i, the INCREASE Study reports changes in FVC from 28.47 mL at baseline to 44.40 mL at Week 16 with a 94% confidence interval of -30.81 to 87.74 at baseline to -25.25 to 114.05 at 16 weeks. (*See* Waxman 2021 at UTC\_PH-ILD\_010825 (Table S6).) A POSA would understand that a 20 mL change falls within the confidence interval at 16 weeks. Thus, administering treprostinil according to the teachings of the 2017 INCREASE Study Description discloses Asserted Claim 10 of the '327 patent. Accordingly, the 2017 INCREASE Study Description combined with Agarwal 2015 and Saggar 2014 renders Asserted Claim 10 of the '327 patent obvious.

**i.       *Claim 11: “The method of claim 1, wherein said administering is performed by a pulsed inhalation device.”***

The 2017 INCREASE Study Description discloses Asserted Claim 11. It describes administering “active treprostinil for inhalation solution” is delivered “via an ultrasonic nebulizer.” (2017 INCREASE Study Description at 10 (Arms and Interventions).) A POSA would have understood that an “ultrasonic nebulizer” is a pulsed inhalation device. Moreover, the INCREASE study confirms that the “ultrasonic nebulizer” described in the 2017 INCREASE Study Description is a pulsed inhalation device as it describes the nebulizer as “an ultrasonic, pulsed-delivery nebulizer.” (Waxman 2021 at UTC\_PH-ILD\_010792.) Accordingly, the 2017 INCREASE Study Description discloses Asserted Claim 11 of the '327 patent, and the 2017 INCREASE Study Description combined with Agarwal 2015 and Saggar 2014 renders Asserted Claim 11 of the '327 patent obvious.

- j. **Claim 15: “The method of claim 1, wherein the effective amount of treprostinil or a pharmaceutically acceptable salt administered to the patient in a single inhalation administration event is from 15 µg to 100 µg.”**

The 2017 INCREASE Study Description discloses Asserted Claim 15. As described in Section III.B.3, the 2017 INCREASE Study Description teaches administering “active inhaled treprostinil” in doses of “approximately 6 mcg per breath” and “[i]nhaled four times daily and titrated up to a maximum of 12 breaths four times daily” which a POSA would understand to be 72 µg in a single administration event. (2017 INCREASE Study Description at 9–11.) A POSA would have further understood that the amount of treprostinil disclosed in the 2017 INCREASE Study Description would be an effective amount based on the dosing regimen commonly used in pulmonary hypertension patients as disclosed in the ’793 patent and the 2009 Tyvaso® Label. A POSA would also understand that 72 µg falls between 15 µg and 100 µg and thus the dosing regimen in the 2017 INCREASE Study Description discloses Asserted Claim 15 of the ’327 patent.

For the same reasons discussed above in Section V.E.3.h, Agarwal 2015 discloses the elements of Asserted Claim 15 of the ’327 patent. Thus, the 2017 INCREASE Study Description combined with Agarwal 2015 renders Asserted Claim 15 of the ’327 patent obvious.

- k. **Claim 16: “The method of claim 15, wherein the single inhalation administration event does not exceed 15 breaths by the patient.”**

For the same reasons discussed above in Asserted Claim 15, the 2017 INCREASE Study Description discloses the elements of Asserted Claim 16 of the ’327 patent.

For the same reasons discussed above in Section V.E.3.i, Agarwal 2015 discloses the elements of Asserted Claim 16 of the ’327 patent.

Thus, these references render Asserted Claim 16 of the ’327 patent obvious.

- I. Claim 17: “The method of claim 1, wherein said administering increases a 6 minutes walk distance of the patient by at least 10 m after 8 weeks of the administering.”**

For the same reasons discussed above in Asserted Claim 2, the 2017 INCREASE Study Description discloses the elements of Asserted Claim 17 of the '327 patent.

For the same reasons discussed above in Section V.E.3.j, Agarwal 2015 discloses the elements of Asserted Claim 17 of the '327 patent.

Thus, these references render Asserted Claim 17 of the '327 patent obvious.

- m. Claim 18: “The method of claim 1, wherein said administering increases a 6 minutes walk distance of the patient by at least 15 m after 12 weeks of the administering.”**

For the same reasons discussed above in Asserted Claim 2, the 2017 INCREASE Study Description discloses the elements of Asserted Claim 18 of the '327 patent.

For the same reasons discussed above in Section V.E.3.k, Agarwal 2015 discloses the elements of Asserted Claim 18 of the '327 patent.

Thus, these references render Asserted Claim 18 of the '327 patent obvious.

- n. Claim 19: “The method of claim 1, wherein said administering increases a 6 minutes walk distance of the patient by at least 15 m after 16 weeks of the administering.”**

For the same reasons discussed above in Asserted Claim 2, the 2017 INCREASE Study Description discloses the elements of Asserted Claim 19 of the '327 patent.

For the same reasons discussed above in Section V.E.3.l, Agarwal 2015 discloses the elements of Asserted Claim 19 of the '327 patent.

Thus, these references render Asserted Claim 19 of the '327 patent obvious.

**CERTIFICATE OF SERVICE**

I certify that I caused copies of the foregoing document to be served on June 3, 2024 upon the following in the manner indicated:

**BY EMAIL**

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*/s/ Sanya Sukduang*  
Sanya Sukduang

# EXHIBIT 8

**From:** Karen Keller  
**Sent:** Friday, December 6, 2024 7:43 PM  
**To:** Flynn, Michael J.  
**Cc:** Nate Hoeschen; Sanya Sukduang  
**Subject:** Re: UTC/Liquidia - Discovery disputes

Michael:

While we appreciate that UTC believes this issue is ripe for the Court's review, given the judge's comments on the meet and confer process during yesterday's hearing, we do not believe that the parties have completed a fulsome meet and confer at this point and that UTC is doing just what J. Fallon advised against, running to the court before trying to work it out. Mr. Jackson was not prepared to tell us on the call today what specifically was "new" in the November contentions that UTC did not have previous notice of (the purpose of contentions) otherthan alleging that certain whole sections or paragraphs were new. It was evident given the email requesting a meet and confer 45 minutes after the contentions were served and the fact that Mr. Jackson had not prepared a redline of the contentions even at the time of the meet and confer, that a thorough review had, in fact, not been done. UTC cold not articulate a specific legal theory that was never previously raised other than Liquidia's obviousness theory of invalidity based on Faria-Urbina 2018. But as Mr. Sukduang stated, Liquidia first disclosed this legal theory on June 3, 2024. UTC then suggested that references to testimony by Drs. Rajan and Rajeev Saggar was "new," but again Liquidia reminded UTC that it's reliance on the testimony of both Saggars was disclosed in its Oct. 30, 2024 Invalidity Contentions and that the updated contentions merely added specific pinpoint citations to the testimony, though not necessary, to provide even more clarity for UTC. UTC further identified Liquidia's lack of a priority position as "new," yet Liquidia also disclosed this theory of invalidity in its Oct. 30 2024 Invalidity Contentions. Moreover, UTC was aware of Liquidia's position based on Liquidia's Interrogatory No. 5 asking UTC for its position and support for the priority date of the '327. Liquidia filed a letter motion with the court to compel a response to the interrogatory, which the Court granted. Liquidia did not receive UTC's position until November 19<sup>th</sup>, after the close of fact discovery. In light of UTC's supplemental interrogatory response, Liquidia courteously and promptly updated its invalidity contentions regarding the priority date a week later.

As you can see, Mr. Sukduang pointed to numerous examples during the call of where certain information that UTC alleged was "new" was in fact disclosed in earlier served contentions. UTC could not explain in any further detail why they believed these theories or factual contentions were new and did not provide any arguments of prejudice to UTC by the allegedly late disclosure. This is not sufficient under the local rule to satisfy the meet and confer process. Liquidia still does not know what UTC will argue in its opening letter to the court as to what is exactly at issue and therefore has no opportunity to provide response to UTC to attempt to resolve the issues. We requested at the meet and confer that UTC provide a letter or table outlining for us what it thinks was never before disclosed and how it did not have notice of the theories or facts prior to the service date of those contentions. We assume that your email earlier today to file the letter with the court means that we won't be receiving that. If UTC intends to proceed without a further meet and confer or providing Liquidia with any further information ahead of reaching out to the court, Liquidia intends to inform the court in its response of UTC's behavior and unwillingness to engage on these issues.

Best,  
Karen

---

**From:** Flynn, Michael J. <mflynn@morrisnichols.com>  
**Date:** Friday, December 6, 2024 at 4:11 PM  
**To:** Karen Keller <kkeller@shawkeller.com>

**Cc:** Nate Hoeschen <[nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com)>

**Subject:** UTC/Liquidia - Discovery disputes

Karen,

As discussed on the call this morning, UTC will ask the Court for a conference on Liquidia's untimely discovery responses. Can you please confirm that the Dec. 17, 18, and 20 dates you provided on Wednesday are still good for you?

---

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# EXHIBIT 9

## Strosnick, Lauren

---

**From:** Jackson, William C <WJackson@goodwinlaw.com>  
**Sent:** Tuesday, December 17, 2024 1:41 PM  
**To:** Sukduang, Sanya; Levi, Eric; Preston, Rachel L  
**Cc:** Alyssa Libetti; Eskola, Melissa; z/Liquidia v UTC 308970-201; kkeller@shawkeller.com; Nate Hoeschen; Habibi, John A; Adykhuis@mwe.com; Sydney McDermott; jvallen@mwe.com; aburrowbridge@mwe.com; Dcarsten@mwe.com; mflynn@morrisnichols.com; DG-ILD; UTCvLiquidia-Del-23cv975  
**Subject:** RE: C.A. No. 23-975-RGA-SRF United Therapeutics Corporation v. Liquidia Technologies, Inc.

### [External]

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Sanya:

This is not about requesting additional time for expert reports. This is about the fact that Liquidia served contentions and discovery responses after the deadlines for doing so. We reject your proposed “compromise” of additional time. It is clear we’re at an impasse. We believe we need to get these issues to the Court ASAP.

**William C Jackson**



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**From:** Sukduang, Sanya <ssukduang@cooley.com>  
**Sent:** Monday, December 16, 2024 3:00 PM  
**To:** Levi, Eric <ELevi@goodwinlaw.com>; Preston, Rachel L <RPreston@cooley.com>  
**Cc:** Alyssa Libetti <alibetti@shawkeller.com>; Eskola, Melissa <meskola@cooley.com>; z/Liquidia v UTC 308970-201 <zLiquidiavUTC308970201@cooley.com>; kkeller@shawkeller.com; Nate Hoeschen <nhoeschen@shawkeller.com>; Habibi, John A <JHabibi@cooley.com>; Adykhuis@mwe.com; Sydney McDermott <Smcdermott@mwe.com>; jvallen@mwe.com; aburrowbridge@mwe.com; Dcarsten@mwe.com; mflynn@morrisnichols.com; DG-ILD <DG-ILD@goodwinlaw.com>; UTCvLiquidia-Del-23cv975 <UTCvLiquidia-Del-23cv975@mwe.com>; Jackson, William C <WJackson@goodwinlaw.com>  
**Subject:** RE: C.A. No. 23-975-RGA-SRF United Therapeutics Corporation v. Liquidia Technologies, Inc.

\*\*\*EXTERNAL\*\*\*

Counsel,

There is apparent disagreement as to UTC’s preparedness during the prior meet and confer and we provided UTC ample opportunity to explain. Moreover, when UTC did explain, it provided examples that were not included in UTC’s December 10, 2024 email. Nonetheless, we disagree with UTC’s position. Liquidia has put UTC on

sufficient notice and UTC does not account for the fact that significant discovery took place after October 30—discovery directly related to Liquidia’s contentions and unavailable before then. Moreover, as Liquidia noted during the meet and confer, UTC’s rigid position will result in exclusion of nearly all infringement and damages evidence and testimony from any forthcoming expert report based on UTC’s own discovery responses.

Liquidia does not believe it needs to withdraw any of its contentions. However, as a compromise, if UTC needs an additional time to prepare its responsive expert reports, Liquidia is willing to reach that agreement and inform the Court. We are not available to confer today, and as you know the parties are preparing for summary judgement and expert reports. To the extent UTC would like to meet and confer on Liquidia’s proposed compromise, please let us know.

Thanks  
Sanya

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**From:** Levi, Eric <[ELevi@goodwinlaw.com](mailto:ELevi@goodwinlaw.com)>  
**Sent:** Monday, December 16, 2024 9:04 AM  
**To:** Preston, Rachel L <[RPreston@cooley.com](mailto:RPreston@cooley.com)>; Sukduang, Sanya <[ssukduang@cooley.com](mailto:ssukduang@cooley.com)>  
**Cc:** Alyssa Libetti <[alibetti@shawkeller.com](mailto:alibetti@shawkeller.com)>; Eskola, Melissa <[meskola@cooley.com](mailto:meskola@cooley.com)>; z/Liquidia v UTC 308970-201 <[zLiquidiavUTC308970201@cooley.com](mailto:zLiquidiavUTC308970201@cooley.com)>; kkeller@shawkeller.com; Nate Hoeschen <[nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com)>; Habibi, John A <[JHabibi@cooley.com](mailto:JHabibi@cooley.com)>; Adykhuis@mwe.com; Sydney McDermott <[Smcdermott@mwe.com](mailto:Smcdermott@mwe.com)>; jvallen@mwe.com; aburrowbridge@mwe.com; Dcarsten@mwe.com; mflynn@morrisnichols.com; DG-ILD <[DG-ILD@goodwinlaw.com](mailto:DG-ILD@goodwinlaw.com)>; UTCvLiquidia-Del-23cv975 <[UTCvLiquidia-Del-23cv975@mwe.com](mailto:UTCvLiquidia-Del-23cv975@mwe.com)>; Jackson, William C <[WJackson@goodwinlaw.com](mailto:WJackson@goodwinlaw.com)>  
**Subject:** RE: C.A. No. 23-975-RGA-SRF United Therapeutics Corporation v. Liquidia Technologies, Inc.

**[External]**

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Counsel,

Thank you for providing a redline comparison between Liquidia’s 10/30/2024 and 12/3/2024 invalidity contentions (“Liquidia’s redline comparison”). We disagree with the remaining substance of your email, which mischaracterizes the parties’ recent December 6, 2024 meet-and-confer and subsequent correspondence.

Contrary to Liquidia’s assertion, UTC was prepared to discuss every difference between Liquidia’s 10/30/2024 and 12/3/2024 invalidity contentions during the December 6 meet-and-confer. As UTC has explained repeatedly, both during the call and subsequently by email on December 10, the new legal theories and evidence added to Liquidia’s October 30 final invalidity contentions are improper and can be readily identified by a redline comparison. Nonetheless, on December 10, to accommodate Liquidia’s request during the parties’ meet-and-confer, UTC identified six specific sections in Liquidia’s December 3 invalidity contentions which UTC will move to strike. These six specific sections were served late in violation of the Scheduling Order, incorporate new theories and evidence, and incorporate arguments that are not pled in Liquidia’s Answer and Counterclaims.

Specific responses to Liquidia’s position on each of the six sections under dispute are set forth below. Liquidia’s addition of these six new sections in its “Final” invalidity contentions after the close of fact discovery is impermissible for the above reasons as well as those discussed during the parties’ December 6 meet-and-confer and by email on December 10.

1. Dr. Smith’s deposition does not excuse Liquidia’s obligation to serve final invalidity contentions by October 30. D.I. 45, ¶3(g)(ii)(2). Liquidia cites no authority to support why its “anticipat[ion of] further supplementation” provides UTC with adequate notice and disclosure, and why such further supplementation outside the Scheduling Order is permissible. Further, Liquidia’s redline comparison and its December 11 email demonstrate that Liquidia’s theory of improper inventorship was not detailed in its October 30 final invalidity contentions, and that Liquidia’s position is based on substantial evidence that was available prior to both Liquidia’s October

30 contentions and the close of fact discovery. There is no reason Liquidia could not have included this argument in its October 30 contentions.

2. Liquidia's redline comparison and its December 11 email demonstrate that Liquidia's theory of anticipation by public use was not detailed in its October 30 final invalidity contentions, and that Liquidia relies on evidence produced and disclosed well before the close of fact discovery. Further, Liquidia cites no authority to support why its "anticipat[ion of] further supplementation" provides UTC with adequate notice and disclosure, and why such further supplementation outside the Scheduling Order is permissible. Liquidia has not provided any explanation why this argument could not have been included in its October 30 contentions.
3. Liquidia's redline comparison and its December 11 email demonstrate that Liquidia's theory of anticipation by Faria-Urbina 2018 was not detailed in its October 30 final invalidity contentions, and that Liquidia relies on evidence produced and disclosed well before the close of fact discovery. Indeed, Liquidia has been aware of the Faria-Urbina 2018 reference since the outset of this litigation. This untimely new argument is improper for all the same reasons discussed above.
4. Liquidia's redline comparison and its December 11 email demonstrate that Liquidia's theory of obviousness by Faria-Urbina 2018 was not detailed in its October 30 final invalidity contentions, and that Liquidia relies on evidence produced and disclosed well before October 30 and the close of fact discovery. This untimely new argument is improper for all the same reasons discussed above.
5. Liquidia's redline comparison and its December 11 email demonstrate that Liquidia's theory of obviousness by the 2017 INCREASE Study Description in combination with Faria-Urbina 2018 or Agarwal 2015 and Saggar 2014 was not detailed in its October 30 final invalidity contentions, and that Liquidia relies on evidence produced and disclosed before October 30 and the close of fact discovery. Further, Liquidia cites no authority to support why assertion of an invalidity theory in an earlier contention followed by removal of that invalidity theory from a final contention provides adequate notice and disclosure. This untimely new argument is improper for all the same reasons discussed above.
6. Dr. Smith's and Mr. Snader's depositions do not excuse Liquidia's obligation to serve final invalidity contentions by October 30. D.I. 45, ¶3(g)(iii)(2). Liquidia cites no authority to support why its reservation of its "inten[tion] to supplement" provides UTC with adequate notice and disclosure, and why such further supplementation outside the Scheduling Order is permissible. Further, Liquidia's redline comparison and its December 11 email demonstrate that Liquidia's theory of inequitable conduct was not detailed in its October 30 final invalidity contentions, and that Liquidia relies on more than the deposition testimony of Dr. Smith and Mr. Snader. Regardless, as UTC explained in detail in its December 13 correspondence, inequitable conduct must be pled with particularity, and Liquidia's new allegations against Dr. Smith are not alleged in Liquidia's counterclaims (D.I. 12). See, e.g., *California Inst. of Tech. v. Broadcom Ltd.*, No. CV 16-3714-GW (AGRX), 2019 WL 8807748, at \*4 (C.D. Cal. July 1, 2019), aff'd, 25 F.4th 976, 991–92 (Fed. Cir. 2022). This means that to the extent Liquidia had wished to make those sorts of new inequitable conduct allegations, it could not just amend its contentions and must instead have sought leave from the Court to amend its pleadings. UTC further notes that the deadline to do so has long since passed.

UTC understands that the parties are at an impasse and require judicial intervention. However, if Liquidia believes another meet-and-confer is necessary, please provide your availability to meet-and-confer on Monday (12/16) or Tuesday (12/17), and please confirm that Liquidia will come prepared to identify what it is willing to strike from its December 3, 2024 invalidity contentions. If Liquidia maintains its unwillingness to strike any portions of its December 3, 2024 invalidity contentions, UTC understands that Liquidia believes the parties are at an impasse and require judicial intervention; thereafter, Michael will connect with Karen to confirm the parties' availability for a hearing.

Best,  
Eric

---

**From:** Preston, Rachel L <[RPreston@cooley.com](mailto:RPreston@cooley.com)>

**Sent:** Wednesday, December 11, 2024 6:12 PM

**To:** Levi, Eric <[ELevi@goodwinlaw.com](mailto:ELevi@goodwinlaw.com)>; Sukduang, Sanya <[ssukduang@cooley.com](mailto:ssukduang@cooley.com)>

**Cc:** Alyssa Libetti <[alibetti@shawkeller.com](mailto:alibetti@shawkeller.com)>; Eskola, Melissa <[meskola@cooley.com](mailto:meskola@cooley.com)>; z/Liquidia v UTC 308970-201

<[zLiquidiaUTC308970201@cooley.com](mailto:zLiquidiaUTC308970201@cooley.com)>; [kkeller@shawkeller.com](mailto:kkeller@shawkeller.com); Nate Hoeschen <[nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com)>;  
Habibi, John A <[JHabibi@cooley.com](mailto:JHabibi@cooley.com)>; [Adykhuis@mwe.com](mailto:Adykhuis@mwe.com); Sydney McDermott <[Smcdermott@mwe.com](mailto:Smcdermott@mwe.com)>;  
[jvallen@mwe.com](mailto:jvallen@mwe.com); [aburrowbridge@mwe.com](mailto:aburrowbridge@mwe.com); [Dcarsten@mwe.com](mailto:Dcarsten@mwe.com); [mflynn@morrisnichols.com](mailto:mflynn@morrisnichols.com); DG-ILD <[DG-ILD@goodwinlaw.com](mailto:DG-ILD@goodwinlaw.com)>; UTCvLiquidia-Del-23cv975 <[UTCvLiquidia-Del-23cv975@mwe.com](mailto:UTCvLiquidia-Del-23cv975@mwe.com)>; Jackson, William C  
<[WJackson@goodwinlaw.com](mailto:WJackson@goodwinlaw.com)>

**Subject:** RE: C.A. No. 23-975-RGA-SRF United Therapeutics Corporation v. Liquidia Technologies, Inc.

\*\*\*EXTERNAL\*\*\*

Counsel,

As we noted during the Dec. 6 meet and confer, Liquidia disagrees with UTC's position and will not withdraw any of its invalidity contentions. During the meet and confer, UTC was unprepared to meaningfully engage in the discussion. UTC had not conducted a comparison of Liquidia's December 3 Invalidity Contentions against its October 30 Invalidity Contentions and as a result, UTC failed to identify with specificity which legal theories it believed to be new, providing only vague, broad references to various sections of Liquidia's contentions as "new." UTC has repeated some of its broad accusations here, which Liquidia made clear were unfounded both during the meet and confer and in the Dec. 6 email from Karen Keller and UTC has now disclosed contentions that were not specifically discussed at the Dec. 6 meet and confer. During the meeting, the parties did not discuss improper inventorship, anticipation by Faria-Urbina 2018, and obviousness by the 2017 INCREASE Study Description in combination with Faria-Urbina 2018, Agarwal 2015, and Saggar 2014.

During the meet and confer, after UTC offered broad stroke identifications of things it deemed as "new," Liquidia asked for more specificity regarding UTC's identifications. In its email, UTC has again only broadly identified sections from Liquidia's contentions it deems "new," without checking the veracity of the allegations. Although Liquidia addressed UTC's broad assertions during the prior meet and confer, Liquidia again addresses each allegation in turn below.

1. Improper Inventorship [Final Contentions § II.C]. UTC's identification of Liquidia's improper inventorship contention as "new" was not discussed at the Dec. 6 meet and confer. Nevertheless, Liquidia addresses it here. Liquidia disclosed this contention in its Oct. 30 2024 Invalidity Contentions stating "Liquidia anticipates further supplementation of its invalidity and unenforceability positions including at least the following: supplementation of Liquidia's defenses, including improper inventorship of the '327 patent[.]" Further, additional testimony to support this issue was obtained from Dr. Smith, who's deposition was mere hours before the close of fact discovery. UTC has cited no authority that contentions need to be updated within hours of obtaining relevant discovery.
2. Anticipation by Prior Public Use [Final Contentions § III]. Liquidia disclosed anticipation by prior public use as early as its June 3, 2024 invalidity contentions in Section III.A.3 titled "Long Before April 2020, Physicians Were Using Inhaled Treprostinil to Treat PH-ILD." The section discloses various instances in the prior art where doctors used inhaled treprostinil to treat PH-ILD prior to 2020 and also includes deposition testimony from Dr. Nathan that he used inhaled treprostinil off-label to treat PH-ILD. Prior public use was also disclosed in Section II.A of Liquidia's Preliminary Injunction Opposition Brief and in Section V.C.2 of Dr. Channick's Declaration supporting the brief. In its Oct. 30, 2024 invalidity contentions, Liquidia incorporated the testimony and exhibits from the depositions that occurred prior to Oct. 30 and further informed UTC it anticipated further supplementation of its invalidity positions. Therefore, UTC was aware of the prior use of Tyvaso, and aware that Liquidia's intent to further supplement.
3. Anticipation by Faria-Urbina 2018 [Final Contentions § VI.E]. Liquidia notes that the parties did not discuss anticipation by Faria-Urbina 2018 during the Dec. 6 meet and confer. Liquidia disclosed its intent to rely on Faria-Urbina 2018 in its June 3 and Oct. 30 contentions indicating an intent to rely on the article for its invalidity theories. UTC has been aware of this prior art reference and Liquidia's reliance upon it since at least the PI stage of this case for invalidity.

4. Obviousness by Faria-Urbina 2018 [Final Contentions § VII.D]. Liquidia's response is the same as above.
5. Obviousness by the 2017 INCREASE Study Description in Combination with Faria-Urbina 2018 or Agarwal 2015 and Saggar 2014 [Final Contentions § VII.G]. Liquidia notes that the parties did not discuss this contention during the Dec. 6 meet and confer. The combination of the 2017 INCREASE Study Description in combination with Agarwal 2015 and Saggar 2014 was previously disclosed in Section V.F of Liquidia's June 3 invalidity contentions. Further, as Liquidia points out above, Faria-Urbina 2018 is not new prior art, and thus the combination of the 2017 INCREASE Study description with Faria-Urbina 2018 and Saggar 2014 is not a new theory.
6. Inequitable Conduct by Peter Smith [Final Contentions § IX.I-M]. Finally, UTC identified Liquidia's inequitable conduct by Peter Smith as new previously, during the meet and confer. Liquidia responded pointing to its Oct. 30 Invalidity Contentions identifying Dr. Smith as an inventor who engaged in inequitable conduct. Indeed, Liquidia informed UTC that it intended to supplement its inequitable conduct allegations "following upcoming depositions, including the depositions of Shaun Snader, Stephen Maebius, Martine Rothblatt, **and the named inventors of the '327 patent.**" Liquidia also notes that Dr. Smith's testimony was not obtained until November 12, 2024, hours before the November 13, close of fact discovery. Further, the deposition of UTC in-house counsel, Shaun Snader, was not conducted until November 26, 2024, **after** the close of fact discovery, where Mr. Snader confirmed that he did not advise the inventors, including Dr. Smith, of their duty to disclose. UTC has not explained how or why they believe Liquidia was required to supplement its contention when the relevant testimony was obtained hours before, and after the close of fact discovery.

Liquidia provided UTC notice and did not include any new prior art or previously undisclosed invalidity positions in its Dec. 3 invalidity contentions. Thus, UTC's complaints of "newness" are hollow. If UTC wishes to meet-and-confer again, Liquidia will happily oblige if UTC intends to direct Liquidia to specific material it considers new, rather than point to generalizations as it did in both the Dec. 6 meet and confer and its Dec. 10 email here.

For completeness, Liquidia highlights that additional contentions were discussed during the Dec. 6 meet and confer and summarizes those discussions here. UTC suggested that deposition pin cites to the testimony by Drs. Rajan and Rajeev Saggar was "new," because it was available to Liquidia before the November 13, 2024 close of fact discovery. Liquidia pointed out to UTC that its reliance on the testimony of both Saggars was disclosed in Liquidia's Oct. 30, 2024 Invalidity Contentions, and Liquidia understands that UTC has withdrawn its complaint regarding the Saggar testimony.

During the meet and confer UTC also identified Liquidia's priority date contention was new. Liquidia pointed out that this was disclosed in its Oct. 30, 2024 Invalidity Contentions. Moreover, during the conference, and as cited in its contention, Liquidia reminded UTC that it provided its position on its alleged entitlement to the April 2020 priority date on November 19, 2024, after the close of fact discovery, because the Court ordered UTC to supplement its response to Liquidia's Interrogatory No. 5. Not only is lack of priority not a "new" allegation, but William Jackson's own Dec. 3 email specifically states that UTC does not intend to seek to strike "amendments and updates that the Court ordered in response to the parties' discovery disputes." Since UTC does not mention the priority date contention in its Dec. 12 email, Liquidia understands that UTC has withdrawn its complaint regarding the priority date contention.

Liquidia also notes that UTC made no complaints of "newness" regarding Liquidia's November 22, 2024 supplemental responses to UTC's Interrogatories No. 2-9 and its December 2, 2024 supplemental response to UTC's Interrogatory No. 1 during the meet and confer. UTC has also not raised issues with these responses below. As such, Liquidia believes UTC is no longer seeking to exclude these interrogatory supplementations.

Finally, UTC has not provided a sufficient reason it should receive word versions of Liquidia's invalidity contentions. Liquidia will not provide UTC with word versions of its invalidity contentions. However, as a courtesy, attached please find a redline compare between the 10/30/2024 contentions and the 12/3/2024 contentions.

Regards,  
Rachel

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**From:** Levi, Eric <[ELevi@goodwinlaw.com](mailto:ELevi@goodwinlaw.com)>  
**Sent:** Tuesday, December 10, 2024 12:13 PM  
**To:** Sukduang, Sanya <[ssukduang@cooley.com](mailto:ssukduang@cooley.com)>  
**Cc:** Alyssa Libetti <[alibetti@shawkeller.com](mailto:alibetti@shawkeller.com)>; Eskola, Melissa <[meskola@cooley.com](mailto:meskola@cooley.com)>; z/Liquidia v UTC 308970-201 <[zLiquidiavUTC308970201@cooley.com](mailto:zLiquidiavUTC308970201@cooley.com)>; kkeller@shawkeller.com; Nate Hoeschen <[nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com)>; Habibi, John A <[JHabibi@cooley.com](mailto:JHabibi@cooley.com)>; Adykhuis@mwe.com; Sydney McDermott <[Smcdermott@mwe.com](mailto:Smcdermott@mwe.com)>; jvallen@mwe.com; aburrowbridge@mwe.com; Dcarsten@mwe.com; mflynn@morrisnichols.com; DG-ILD <[DG-ILD@goodwinlaw.com](mailto:DG-ILD@goodwinlaw.com)>; UTCvLiquidia-Del-23cv975 <[UTCvLiquidia-Del-23cv975@mwe.com](mailto:UTCvLiquidia-Del-23cv975@mwe.com)>; Jackson, William C <[WJackson@goodwinlaw.com](mailto:WJackson@goodwinlaw.com)>  
**Subject:** RE: C.A. No. 23-975-RGA-SRF United Therapeutics Corporation v. Liquidia Technologies, Inc.

**[External]**

Counsel,

Following-up on our meet-and-confer last Friday, December 6, UTC intends to move the Court to strike the following arguments from Liquidia's December 3, 2024 Final Invalidity Contentions ("Final Contentions"):

1. Improper Inventorship [Final Contentions § II.C]
2. Anticipation by Prior Public Use [Final Contentions § III]
3. Anticipation by Faria-Urbina 2018 [Final Contentions § VI.E]
4. Obviousness by Faria-Urbina 2018 [Final Contentions § VII.D]
5. Obviousness by the 2017 INCREASE Study Description in Combination with Faria-Urbina 2018 or Agarwal 2015 and Saggar 2014 [Final Contentions § VII.G]
6. Inequitable Conduct by Peter Smith [Final Contentions § IX.I-M]

Liquidia failed to raise any of these arguments prior to the close of fact discovery on November 13 (see D.I. 45, ¶13(a)), and during the parties' meet-and-confer within 7 days of the Markman Order on October 23 (see D.I. 45, ¶13(g)(iii)). Moreover, as Liquidia's Final Contentions make clear, each of these arguments relies heavily on evidence that was in Liquidia's possession prior to the close of fact discovery. These arguments are therefore untimely raised and should be struck from Liquidia's Final Contentions. See, e.g., *Chevron (HK) Ltd. v. One World Techs., Inc.*, No. CV 19-1293-GBW, 2023 WL 2372938, at \*3 (D. Del. Mar. 6, 2023). Finally, Liquidia's new inequitable conduct allegations against Peter Smith are not only entirely unfounded in fact, but also entirely absent from Liquidia's operative inequitable conduct pleadings (D.I. 12). The time for free amendment of pleadings has long since passed, and Liquidia must remove these baseless, unpled allegations from its Final Contentions. See, e.g., *CSB-System Intern. Inc. v. SAP Am., Inc.*, No. CIV.A. 10-2156, 2012 WL 1645582, at \*6 (E.D. Pa. May 10, 2012); *ChemFree Corp. v. J. Walter, Inc.*, No. CIV 104-CV-3711-JTC, 2008 WL 3884365, at \*2 (N.D. Ga. June 10, 2008); *Lab'y Skin Care, Inc. v. Ltd. Brands, Inc.*, No. CIV A 06-601-JJF, 2009 WL 2524577, at \*3 (D. Del. Aug. 17, 2009).

Please advise no later than end of business tomorrow (Dec. 11) whether Liquidia will agree to withdraw any of the arguments listed above. If Liquidia declines to withdraw all arguments listed above, UTC again requests that Liquidia provide word versions of its October 30 and December 3 Invalidity Contentions for clarity of presentation to the Court, which counsel for UTC previously requested during the parties' December 6 meet-and-confer. To the extent Liquidia believes a further meet-and-confer is necessary, please provide your earliest availability for same.

Best,  
Eric

---

**From:** Jackson, William C <[WJackson@goodwinlaw.com](mailto:WJackson@goodwinlaw.com)>  
**Sent:** Wednesday, December 4, 2024 12:53 PM  
**To:** Sukduang, Sanya <[ssukduang@cooley.com](mailto:ssukduang@cooley.com)>  
**Cc:** Alyssa Libetti <[alibetti@shawkeller.com](mailto:alibetti@shawkeller.com)>; Eskola, Melissa <[meskola@cooley.com](mailto:meskola@cooley.com)>; z/Liquidia v UTC 308970-201 <[zLiquidiavUTC308970201@cooley.com](mailto:zLiquidiavUTC308970201@cooley.com)>; kkeller@shawkeller.com; Nate Hoeschen <[nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com)>; Habibi, John A <[JHabibi@cooley.com](mailto:JHabibi@cooley.com)>; Adykhuis@mwe.com; Sydney McDermott <[Smcdermott@mwe.com](mailto:Smcdermott@mwe.com)>; jvallen@mwe.com; aburrowbridge@mwe.com; Dcarsten@mwe.com; mflynn@morrisnichols.com; DG-ILD <[DG-ILD@goodwinlaw.com](mailto:DG-ILD@goodwinlaw.com)>; UTCvLiquidia-Del-23cv975 <[UTCvLiquidia-Del-23cv975@mwe.com](mailto:UTCvLiquidia-Del-23cv975@mwe.com)>  
**Subject:** RE: C.A. No. 23-975-RGA-SRF United Therapeutics Corporation v. Liquidia Technologies, Inc.

We will send an invite for at 9:30am.

**William C Jackson**



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---

**From:** Sukduang, Sanya <[ssukduang@cooley.com](mailto:ssukduang@cooley.com)>  
**Sent:** Tuesday, December 3, 2024 8:26 PM  
**To:** Jackson, William C <[WJackson@goodwinlaw.com](mailto:WJackson@goodwinlaw.com)>  
**Cc:** Alyssa Libetti <[alibetti@shawkeller.com](mailto:alibetti@shawkeller.com)>; Eskola, Melissa <[meskola@cooley.com](mailto:meskola@cooley.com)>; z/Liquidia v UTC 308970-201 <[zLiquidiavUTC308970201@cooley.com](mailto:zLiquidiavUTC308970201@cooley.com)>; kkeller@shawkeller.com; Nate Hoeschen <[nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com)>; Habibi, John A <[JHabibi@cooley.com](mailto:JHabibi@cooley.com)>; Adykhuis@mwe.com; Sydney McDermott <[Smcdermott@mwe.com](mailto:Smcdermott@mwe.com)>; jvallen@mwe.com; aburrowbridge@mwe.com; Dcarsten@mwe.com; mflynn@morrisnichols.com; DG-ILD <[DG-ILD@goodwinlaw.com](mailto:DG-ILD@goodwinlaw.com)>; UTCvLiquidia-Del-23cv975 <[UTCvLiquidia-Del-23cv975@mwe.com](mailto:UTCvLiquidia-Del-23cv975@mwe.com)>  
**Subject:** Re: C.A. No. 23-975-RGA-SRF United Therapeutics Corporation v. Liquidia Technologies, Inc.

\*\*\*EXTERNAL\*\*\*

Counsel

We disagree with your position. We can be available Dec 6 between 9:15-11:00 am.

Sanya

On Dec 3, 2024, at 4:18 PM, Jackson, William C <[WJackson@goodwinlaw.com](mailto:WJackson@goodwinlaw.com)> wrote:

**[External]**

Counsel for Liquidia:

Fact discovery closed weeks ago. Liquidia has now improperly sought to amend and update its interrogatories and contentions several times following the close of fact discovery. Liquidia has provided no justification for its new interrogatory responses and contentions. To the degree Liquidia believed it needed to supplement or update its discovery responses, those supplements and updates were due before the close of fact discovery.

Consequently, Liquidia may not rely on those amendments and updates. UTC intends to move to strike any and all such amendments and updates (other than the amendments and updates that the Court ordered in response to the parties' discovery disputes).

**Please let us know if you are available for a meet and confer tomorrow, December 4.**

**William C Jackson**

<image001.png>

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m +1 202 270 6622  
f +1 202 478 0819  
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<image004.png>

<image005.png>

<image006.png>

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**From:** Alyssa Libetti <[alibetti@shawkeller.com](mailto:alibetti@shawkeller.com)>

**Sent:** Tuesday, December 3, 2024 3:37 PM

**To:** Horowitz, Adam J. <[AHorowitz@goodwinlaw.com](mailto:AHorowitz@goodwinlaw.com)>; [aburrowbridge@mwe.com](mailto:aburrowbridge@mwe.com); [Adykhuis@mwe.com](mailto:Adykhuis@mwe.com); Courtney Cecile Seams (<[cseams@mwe.com](mailto:cseams@mwe.com)>) <[cseams@mwe.com](mailto:cseams@mwe.com)>; DG-ILD <[DG-ILD@goodwinlaw.com](mailto:DG-ILD@goodwinlaw.com)>; [Dcarsten@mwe.com](mailto:Dcarsten@mwe.com); Levi, Eric <[ELevi@goodwinlaw.com](mailto:ELevi@goodwinlaw.com)>; Romeo, Eric <[ERomeo@goodwinlaw.com](mailto:ERomeo@goodwinlaw.com)>; Blumenfeld, Jack <[JBlumenfeld@morrisnichols.com](mailto:JBlumenfeld@morrisnichols.com)>; Cheng, Katherine <[KatherineCheng@goodwinlaw.com](mailto:KatherineCheng@goodwinlaw.com)>; [kpappas@mwe.com](mailto:kpappas@mwe.com); Kyle Sorenson ,PhD (<[ksorenson@mwe.com](mailto:ksorenson@mwe.com)>); [ksorenson@mwe.com](mailto:ksorenson@mwe.com); Lillian Spetrino <[Ispetrino@mwe.com](mailto:Ispetrino@mwe.com)>; Lobel, Louis <[LLobel@goodwinlaw.com](mailto:LLobel@goodwinlaw.com)>; Michael J. Flynn <[mflynn@morrisnichols.com](mailto:mflynn@morrisnichols.com)>; [mnat\\_ip\\_efiling@morrisnichols.com](mailto:mnat_ip_efiling@morrisnichols.com); [UTCvLiquidia-Del-23cv975@mwe.com](mailto:UTCvLiquidia-Del-23cv975@mwe.com) <[UTCvLiquidia-Del-23cv975@mwe.com](mailto:UTCvLiquidia-Del-23cv975@mwe.com)>; Jackson, William C <[WJackson@goodwinlaw.com](mailto:WJackson@goodwinlaw.com)>

**Subject:** C.A. No. 23-975-RGA-SRF United Therapeutics Corporation v. Liquidia Technologies, Inc.

\*\*\*EXTERNAL\*\*\*

Good afternoon,

Please find attached the following documents for service:

1. HIGHLY CONFIDENTIAL - Defendant Liquidia Technologies, Inc's Final Invalidity Contentions
2. Notice of Service

The supplements to these contentions are made in view of additional written and deposition discovery and testimony obtained following the prior supplementation on October 30, 2024

Thank you.

**Alyssa M. Libetti**, Litigation Paralegal | SHAW KELLER LLP  
I.M. Pei Building | 1105 North Market Street, 12<sup>th</sup> Floor | Wilmington, DE 19801  
P 302.298.0707 | F 302.300.4026 | [alibetti@shawkeller.com](mailto:alibetti@shawkeller.com) | [www.shawkeller.com](http://www.shawkeller.com)

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# EXHIBIT 10

## Strosnick, Lauren

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**From:** McDermott, Sydney <Smcdermott@mwe.com>  
**Sent:** Tuesday, October 22, 2024 1:28 PM  
**To:** Preston, Rachel L; Pappas, Katherine; Dykhuis, Art; Vallen, Jake; Davies, Jonathan; Minn, Robert; Burrowbridge, Adam; Carsten, Douglas; WJackson@goodwinlaw.com; mflynn@morrisnichols.com  
**Cc:** z/Liquidia v UTC 308970-201; DG-ILD; UTCvLiquidia-Del-23cv975  
**Subject:** RE: UTC v. Liquidia (23-975) - Deposition dates for witnesses

### [External]

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Counsel,

So far, you have not provided dates for the Moomaw, Gallant, Adair, or Snow depositions requested by UTC. Nor have you confirmed that you are looking into those dates. Please confirm you are working on dates for those witnesses today and provide the dates as soon as possible.

Regarding additional depositions requested by Liquidia, we will offer:

- Tapson on November 5 in Santa Monica, CA
- Laliberte on November 8 in Raleigh, NC
- Wade on November 8 in Raleigh, NC
- Barton on November 14 in Dallas, TX
- DeAngelis on November 15 in Raleigh, NC
- Nainani on November 15 in Washington, D.C.

SYDNEY MCDERMOTT (SHE/HER/HERS)

Associate

**McDermott Will & Emery LLP** The McDermott Building, 500 North Capitol Street, NW, Washington, DC 20001-1531

Tel +1 202 756 8045 Email [smcdermott@mwe.com](mailto:smcdermott@mwe.com)

[Website](#) | [vCard](#) | [LinkedIn](#)

---

**From:** Preston, Rachel L <RPreston@cooley.com>

**Sent:** Monday, October 21, 2024 12:47 PM

**To:** McDermott, Sydney <Smcdermott@mwe.com>; Pappas, Katherine <Kpappas@mwe.com>; Dykhuis, Art <Adykhuis@mwe.com>; Vallen, Jake <Jvallen@mwe.com>; Davies, Jonathan <jdavies@cooley.com>; Minn, Robert <rminn@cooley.com>; Burrowbridge, Adam <Aburrowbridge@mwe.com>; Carsten, Douglas <Dcarsten@mwe.com>; WJackson@goodwinlaw.com; mflynn@morrisnichols.com

**Cc:** z/Liquidia v UTC 308970-201 <zLiquidia v UTC 308970-201@cooley.com>; DG-ILD <DG-ILD@goodwinlaw.com>; UTCvLiquidia-Del-23cv975 <UTCvLiquidia-Del-23cv975@mwe.com>

**Subject:** RE: UTC v. Liquidia (23-975) - Deposition dates for witnesses

### [ External Email ]

Counsel,

We can accept the following dates, and will continue to update our availability for the remainder:

- Bunce 10/29 – Raleigh, NC

- Maebius 10/31 – Washington DC (on the condition that to the extent Judge Fallon Orders UTC to unredact the documents subject to the Snader letter motion that UTC produce such unredacted documents by October 29)
- Patterson 11/5 – Washington DC
- Peterson 11/6 – Raleigh, NC
- Deng 11/12 – Raleigh, NC
- Bottorff 11/12 – Raleigh, NC
- Smith 11/13 – Raleigh, NC (subject to taking a break to conduct the 11/13 discovery conference with Judge Fallon)

Further, in light of UTC's updated disclosures, please provide dates and locations for Kiernan De Angelis, Kevin Laliberte, and Vijay Nainani. We are also waiting for dates for Waxman, Tapson and Wade.

Regards,  
Rachel

---

**From:** McDermott, Sydney <[Smcdermott@mwe.com](mailto:Smcdermott@mwe.com)>  
**Sent:** Sunday, October 20, 2024 1:46 PM  
**To:** Preston, Rachel L <[RPRESTON@cooley.com](mailto:RPRESTON@cooley.com)>; Pappas, Katherine <[Kpappas@mwe.com](mailto:Kpappas@mwe.com)>; Dykhuis, Art <[Adykhuis@mwe.com](mailto:Adykhuis@mwe.com)>; Vallen, Jake <[Jvallen@mwe.com](mailto:Jvallen@mwe.com)>; Davies, Jonathan <[jdavies@cooley.com](mailto:jdavies@cooley.com)>; Minn, Robert <[rminn@cooley.com](mailto:rminn@cooley.com)>; Burrowbridge, Adam <[Aburrowbridge@mwe.com](mailto:Aburrowbridge@mwe.com)>; Carsten, Douglas <[Dcarsten@mwe.com](mailto:Dcarsten@mwe.com)>; [WJackson@goodwinlaw.com](mailto:WJackson@goodwinlaw.com); [mflynn@morrisnichols.com](mailto:mflynn@morrisnichols.com)  
**Cc:** z/Liquidia v UTC 308970-201 <[zLiquidiavUTC308970201@cooley.com](mailto:zLiquidiavUTC308970201@cooley.com)>; DG-ILD <[DG-ILD@goodwinlaw.com](mailto:DG-ILD@goodwinlaw.com)>; UTCvLiquidia-Del-23cv975 <[UTCvLiquidia-Del-23cv975@mwe.com](mailto:UTCvLiquidia-Del-23cv975@mwe.com)>  
**Subject:** Re: UTC v. Liquidia (23-975) - Deposition dates for witnesses

**[External]**

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Counsel,

We disagree with your characterizations of the parties' discovery conduct regarding Drs. Saggar and Smith. Notably absent from your email is any acknowledgement of the substantial volume of regulatory and clinical documents Liquidia produced the weekend prior to the deposition of its 30(b)(6) witness Dr. Saggar—including 729 documents on the evening of Oct. 11 (Friday) and 232 documents on the evening of Oct. 12 (Saturday), respectively. Despite receiving these documents after working hours and on a weekend, UTC nonetheless showed up prepared to take Dr. Saggar's deposition on Oct. 16. Your refusal to make a similar accommodation for Dr. Smith is yet another example of Liquidia's consistent unwillingness to practice what it preaches.

UTC will offer Dr. Smith for deposition in Raleigh on Nov. 13. While we believe that Liquidia is represented by a sufficient number of outside counsel to conduct the deposition simultaneously with the discovery conference that day, we can accommodate a short recess for the hearing should Liquidia deem it necessary.

SYDNEY MCDERMOTT (SHE/HER/HERS)

Associate

**McDermott Will & Emery LLP** The McDermott Building, 500 North Capitol Street, NW, Washington, DC 20001-1531

**Tel** +1 202 756 8045   **Email** [smcdermott@mwe.com](mailto:smcdermott@mwe.com)

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**From:** Preston, Rachel L <[RPRESTON@COOLEY.COM](mailto:RPRESTON@COOLEY.COM)>

**Sent:** Friday, October 18, 2024 4:50 PM

**To:** McDermott, Sydney <[SMCDERMOTT@mwe.com](mailto:SMCDERMOTT@mwe.com)>; Pappas, Katherine <[KPAPPAS@mwe.com](mailto:KPAPPAS@mwe.com)>; Dykhuis, Art <[ADYKHUIS@mwe.com](mailto:ADYKHUIS@mwe.com)>; Vallen, Jake <[JVALLEN@mwe.com](mailto:JVALLEN@mwe.com)>; Davies, Jonathan <[JDAVIES@COOLEY.COM](mailto:JDAVIES@COOLEY.COM)>; Minn, Robert <[RMINN@COOLEY.COM](mailto:RMINN@COOLEY.COM)>; Burrowbridge, Adam <[ABURROWBRIDGE@mwe.com](mailto:ABURROWBRIDGE@mwe.com)>; Carsten, Douglas <[DCARSTEN@mwe.com](mailto:DCARSTEN@mwe.com)>; [WJACKSON@goodwinlaw.com](mailto:WJACKSON@goodwinlaw.com) <[WJACKSON@goodwinlaw.com](mailto:WJACKSON@goodwinlaw.com)>; [MFLYNN@MORRISNICHOLS.COM](mailto:MFLYNN@MORRISNICHOLS.COM) <[MFLYNN@MORRISNICHOLS.COM](mailto:MFLYNN@MORRISNICHOLS.COM)>

**Cc:** z/Liquidia v UTC 308970-201 <[zLiquidiavUTC308970201@cooley.com](mailto:zLiquidiavUTC308970201@cooley.com)>; DG-ILD <[DG-ILD@goodwinlaw.com](mailto:DG-ILD@goodwinlaw.com)>; UTCvLiquidia-Del-23cv975 <[UTCvLiquidia-Del-23cv975@mwe.com](mailto:UTCvLiquidia-Del-23cv975@mwe.com)>

**Subject:** RE: UTC v. Liquidia (23-975) - Deposition dates for witnesses

**[ External Email ]**

Counsel,

Your attempt to put the blame on Liquidia is unfounded. We have repeatedly asked UTC regarding the production of custodial documents and as UTC pointed out, it belatedly (by two months) produced at least **2000** documents since October 8 concerning Dr. Smith, with more to come. UTC provided that notification last night and we promptly responded this morning concerning Dr. Smith. Further, Liquidia promptly, within 24 hours of receiving UTC's 30(b)(6) notice, informed UTC that Dr. Saggar would be designated. That timing is a function of UTC's service of its 30(b)(6) requests, not Liquidia's response. UTC complains of a production of "hundreds" of documents 72 hours before Dr. Saggar's deposition, but we note that UTC continued to complain certain documents were not previously produced when in fact they were. (See R. Minn's 10/15/24 Email responding to S. McDermott's 10/15/24 Email.)

We will not be proceeding on October 22<sup>nd</sup>. As for Nov. 13, a hearing before Judge Fallon is scheduled for the same day. As such, UTC may need to accommodate a break during Dr. Smith's deposition if it were to occur that day. Please confirm UTC will agree.

Regards,  
Rachel

---

**From:** McDermott, Sydney <[SMCDERMOTT@mwe.com](mailto:SMCDERMOTT@mwe.com)>

**Sent:** Friday, October 18, 2024 3:44 PM

**To:** Preston, Rachel L <[RPRESTON@COOLEY.COM](mailto:RPRESTON@COOLEY.COM)>; Pappas, Katherine <[KPAPPAS@mwe.com](mailto:KPAPPAS@mwe.com)>; Dykhuis, Art <[ADYKHUIS@mwe.com](mailto:ADYKHUIS@mwe.com)>; Vallen, Jake <[JVALLEN@mwe.com](mailto:JVALLEN@mwe.com)>; Davies, Jonathan <[JDAVIES@COOLEY.COM](mailto:JDAVIES@COOLEY.COM)>; Minn, Robert <[RMINN@COOLEY.COM](mailto:RMINN@COOLEY.COM)>; Burrowbridge, Adam <[ABURROWBRIDGE@mwe.com](mailto:ABURROWBRIDGE@mwe.com)>; Carsten, Douglas <[DCARSTEN@mwe.com](mailto:DCARSTEN@mwe.com)>; [WJACKSON@goodwinlaw.com](mailto:WJACKSON@goodwinlaw.com) <[WJACKSON@goodwinlaw.com](mailto:WJACKSON@goodwinlaw.com)>; [MFLYNN@MORRISNICHOLS.COM](mailto:MFLYNN@MORRISNICHOLS.COM) <[MFLYNN@MORRISNICHOLS.COM](mailto:MFLYNN@MORRISNICHOLS.COM)>

**Cc:** z/Liquidia v UTC 308970-201 <[zLiquidiavUTC308970201@cooley.com](mailto:zLiquidiavUTC308970201@cooley.com)>; DG-ILD <[DG-ILD@goodwinlaw.com](mailto:DG-ILD@goodwinlaw.com)>; UTCvLiquidia-Del-23cv975 <[UTCvLiquidia-Del-23cv975@mwe.com](mailto:UTCvLiquidia-Del-23cv975@mwe.com)>

**Subject:** RE: UTC v. Liquidia (23-975) - Deposition dates for witnesses

**[External]**

Counsel,

For the second time, you have refused to take a previously-scheduled deposition with little notice. This pattern of behavior represents a profound inconvenience to UTC's witnesses, who must accommodate changes to their schedule at the last minute. Liquidia has known about Dr. Smith's deposition availability since October 8. Liquidia is available and capable of taking Dr. Smith's deposition on October 22. Moreover, despite Liquidia's own insufficient and late document productions, UTC has proceeded with depositions of Liquidia's witnesses as scheduled. This notably includes the October 16 deposition of Dr. Rajeev Saggar, who was designated on no less

than twelve 30(b)(6) topics and for whom Liquidia was still producing hundreds of documents less than 72 hours in advance of his deposition. When UTC raised the prejudice caused by the timing of Liquidia's document production, Liquidia refused to postpone the deposition and insisted that it proceed as scheduled or not at all. Further, as Dr. Saggar's testimony established, it appears that Liquidia still has documents to produce related to his 30(b)(6) topics. Discovery is a two-way street, and Liquidia cannot reasonably refuse to show up for Dr. Smith's deposition after demanding that UTC proceed with Dr. Saggar's deposition under similar circumstances.

If Liquidia persists in its refusal to depose Dr. Smith on October 22, UTC will make Dr. Smith available on November 13, in Raleigh, NC and at no other time. Please confirm by close of business today whether Liquidia will be deposing Dr. Smith on October 22 or on November 13.

SYDNEY MCDERMOTT (SHE/HER/HERS)

Associate

**McDermott Will & Emery LLP** The McDermott Building, 500 North Capitol Street, NW, Washington, DC 20001-1531

**Tel** +1 202 756 8045   **Email** smcdermott@mwe.com

[Website](#) | [vCard](#) | [LinkedIn](#)

---

**From:** Preston, Rachel L <[RPRESTON@COOLEY.COM](mailto:RPRESTON@COOLEY.COM)>

**Sent:** Friday, October 18, 2024 10:16 AM

**To:** Pappas, Katherine <[KPAPPAS@MWE.COM](mailto:KPAPPAS@MWE.COM)>; McDermott, Sydney <[SMCDERMOTT@MWE.COM](mailto:SMCDERMOTT@MWE.COM)>; Dykhuis, Art <[ADYKHUIS@MWE.COM](mailto:ADYKHUIS@MWE.COM)>; Vallen, Jake <[JVALLEN@MWE.COM](mailto:JVALLEN@MWE.COM)>; Davies, Jonathan <[JDAVIES@COOLEY.COM](mailto:JDAVIES@COOLEY.COM)>; Minn, Robert <[RMINN@COOLEY.COM](mailto:RMINN@COOLEY.COM)>; Burrowbridge, Adam <[ABURROWBRIDGE@MWE.COM](mailto:ABURROWBRIDGE@MWE.COM)>; Carsten, Douglas <[DCARSTEN@MWE.COM](mailto:DCARSTEN@MWE.COM)>; [WJACKSON@GOODWINLAW.COM](mailto:WJACKSON@GOODWINLAW.COM); [MFLYNN@MORRISNICHOLS.COM](mailto:MFLYNN@MORRISNICHOLS.COM)

**Cc:** z/Liquidia v UTC 308970-201 <[ZLIQUIDIAVUTC308970201@COOLEY.COM](mailto:ZLIQUIDIAVUTC308970201@COOLEY.COM)>; DG-ILD <[DG-ILD@GOODWINLAW.COM](mailto:DG-ILD@GOODWINLAW.COM)>; UTCvLiquidia-Del-23cv975 <[UTCVLIQUIDIAD-DEL-23CV975@MWE.COM](mailto:UTCVLIQUIDIAD-DEL-23CV975@MWE.COM)>

**Subject:** RE: UTC v. Liquidia (23-975) - Deposition dates for witnesses

[ External Email ]

Counsel,

Thank you for your email updating us on your document production. However, since October 8<sup>th</sup> you have produced at least 15,000 pages of documents from Peter Smith, a named inventor, and indicated that more documents are expected by EOD today. The bulk of these documents were produced just this past week. There is simply no reason why nearly all of the documents from a named inventor were produced two months after the substantial completion of document production. Liquidia cannot accept the October 22<sup>nd</sup> date for Dr. Smith. Thus, please provide an alternate date for his deposition.

Regards,  
Rachel

---

**From:** Pappas, Katherine <[KPAPPAS@MWE.COM](mailto:KPAPPAS@MWE.COM)>

**Sent:** Thursday, October 17, 2024 3:09 PM

**To:** Preston, Rachel L <[RPRESTON@COOLEY.COM](mailto:RPRESTON@COOLEY.COM)>; McDermott, Sydney <[SMCDERMOTT@MWE.COM](mailto:SMCDERMOTT@MWE.COM)>; Dykhuis, Art <[ADYKHUIS@MWE.COM](mailto:ADYKHUIS@MWE.COM)>; Vallen, Jake <[JVALLEN@MWE.COM](mailto:JVALLEN@MWE.COM)>; Davies, Jonathan <[JDAVIES@COOLEY.COM](mailto:JDAVIES@COOLEY.COM)>; Minn, Robert <[RMINN@COOLEY.COM](mailto:RMINN@COOLEY.COM)>; Burrowbridge, Adam <[ABURROWBRIDGE@MWE.COM](mailto:ABURROWBRIDGE@MWE.COM)>; Carsten, Douglas <[DCARSTEN@MWE.COM](mailto:DCARSTEN@MWE.COM)>; [WJACKSON@GOODWINLAW.COM](mailto:WJACKSON@GOODWINLAW.COM); [MFLYNN@MORRISNICHOLS.COM](mailto:MFLYNN@MORRISNICHOLS.COM)

**Cc:** z/Liquidia v UTC 308970-201 <[ZLIQUIDIAVUTC308970201@COOLEY.COM](mailto:ZLIQUIDIAVUTC308970201@COOLEY.COM)>; DG-ILD <[DG-ILD@GOODWINLAW.COM](mailto:DG-ILD@GOODWINLAW.COM)>; UTCvLiquidia-Del-23cv975 <[UTCVLIQUIDIAD-DEL-23CV975@MWE.COM](mailto:UTCVLIQUIDIAD-DEL-23CV975@MWE.COM)>

**Subject:** RE: UTC v. Liquidia (23-975) - Deposition dates for witnesses

[External]

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Counsel,

First, you ask for confirmation that UTC has completed its productions of “documents pertaining to the RFPs UTC has previously agreed to produce”—Liquidia served additional RFPs only last week. UTC is still evaluating those requests and therefore is not yet able to provide a date certain regarding the completion of its document productions at this time. To the extent that you’re asking solely about RFPs from Liquidia’s first set of requests (Nos. 1-75), your question plainly seeks more than UTC is obligated to provide. UTC is not obligated to collect from every deponent as a custodian and produce documents untethered to Liquidia’s document requests. Nevertheless, UTC is producing documents consistent with a reasonable collection and review in response to Liquidia’s overbroad, vague, and unduly burdensome RFPs as served—which Liquidia has largely refused to meaningfully narrow. And in an effort to avoid burdening the court with unnecessary disputes, UTC is endeavoring to produce documents from its custodians sufficiently in advance of the corresponding dates that UTC has offered for their depositions.

To date, UTC has produced 2000 custodial documents from Peter Smith and is anticipating completing Smith custodial document production by EOD Friday (10/18) at the latest. We intend to continue rolling production(s) out as quickly as possible.

We have provided below the same listing of witnesses (minus Barton) with locations. With respect to Barton, we are working to identify a new date and will follow up when we have it—his deposition will likely be in Dallas, but we will confirm when providing a new date.

- Byrd 10/15 (completed)
- Smith 10/22 – Raleigh, NC
- Bunce 10/29 – Raleigh, NC
- Maebius 10/31 – Washington DC
- Patterson 11/5 – Washington DC
- Peterson 11/6 – Raleigh, NC
- Deng 11/12 – Raleigh, NC
- Bottorff 11/12 – Raleigh, NC

KATHY PAPPAS

Associate

**McDermott Will & Emery LLP** 18565 Jamboree Road, Suite 250, Irvine, CA 92612-2565

Tel +1 949 989 6361 Email [kpappas@mwe.com](mailto:kpappas@mwe.com)

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---

**From:** Preston, Rachel L <[RPRESTON@COOLEY.COM](mailto:RPRESTON@COOLEY.COM)>

**Sent:** Wednesday, October 16, 2024 7:37 AM

**To:** Pappas, Katherine <[KPAPPAS@mwe.com](mailto:KPAPPAS@mwe.com)>; McDermott, Sydney <[SMCDERMOTT@mwe.com](mailto:SMCDERMOTT@mwe.com)>; Dykhuis, Art <[ADYKHUIS@mwe.com](mailto:ADYKHUIS@mwe.com)>; Vallen, Jake <[JVALLEN@mwe.com](mailto:JVALLEN@mwe.com)>; Davies, Jonathan <[JDAVIES@COOLEY.COM](mailto:JDAVIES@COOLEY.COM)>; Minn, Robert <[RMINN@COOLEY.COM](mailto:RMINN@COOLEY.COM)>; Burrowbridge, Adam <[ABURROWBRIDGE@mwe.com](mailto:ABURROWBRIDGE@mwe.com)>; Carsten, Douglas <[DCARSTEN@mwe.com](mailto:DCARSTEN@mwe.com)>; [WJACKSON@goodwinlaw.com](mailto:WJACKSON@goodwinlaw.com); [MFLYNN@MORRISNICHOLS.COM](mailto:MFLYNN@MORRISNICHOLS.COM)

**Cc:** z/Liquidia v UTC 308970-201 <[zLiquidiavUTC308970201@cooley.com](mailto:zLiquidiavUTC308970201@cooley.com)>; DG-ILD <[DG-ILD@goodwinlaw.com](mailto:DG-ILD@goodwinlaw.com)>; UTCvLiquidia-Del-23cv975 <[UTCvLiquidia-Del-23cv975@mwe.com](mailto:UTCvLiquidia-Del-23cv975@mwe.com)>

**Subject:** RE: UTC v. Liquidia (23-975) - Deposition dates for witnesses

[ External Email ]

Counsel,

Please confirm that UTC has completed its production of custodial documents for Peter Smith, the remaining custodians, and documents pertaining to the RFPs UTC previously agreed to produce. If UTC anticipates further production, please provide a date certain as to when its production will be complete. We are reviewing the dates provided, but please provide locations for those witnesses where a location has not yet been identified. Additionally, please provide a new date for David Barton as counsel for Liquidia is unavailable on 10/25.

Regards,  
Rachel

---

**From:** Pappas, Katherine <[kpappas@mwe.com](mailto:kpappas@mwe.com)>  
**Sent:** Tuesday, October 15, 2024 10:02 PM  
**To:** McDermott, Sydney <[Smcdermott@mwe.com](mailto:Smcdermott@mwe.com)>; Dykhuis, Art <[Adykhuis@mwe.com](mailto:Adykhuis@mwe.com)>; Vallen, Jake <[Jvallen@mwe.com](mailto:Jvallen@mwe.com)>; Davies, Jonathan <[jdavies@cooley.com](mailto:jdavies@cooley.com)>; Minn, Robert <[rminn@cooley.com](mailto:rminn@cooley.com)>; Burrowbridge, Adam <[Aburrowbridge@mwe.com](mailto:Aburrowbridge@mwe.com)>; Carsten, Douglas <[Dcarsten@mwe.com](mailto:Dcarsten@mwe.com)>; [WJackson@goodwinlaw.com](mailto:WJackson@goodwinlaw.com); [mflynn@morrisnichols.com](mailto:mflynn@morrisnichols.com)  
**Cc:** z/Liquidia v UTC 308970-201 <[zLiquidiavUTC308970201@cooley.com](mailto:zLiquidiavUTC308970201@cooley.com)>; DG-ILD <[DG-ILD@goodwinlaw.com](mailto:DG-ILD@goodwinlaw.com)>; UTCvLiquidia-Del-23cv975 <[UTCvLiquidia-Del-23cv975@mwe.com](mailto:UTCvLiquidia-Del-23cv975@mwe.com)>  
**Subject:** RE: UTC v. Liquidia (23-975) - Deposition dates for witnesses

**[External]**

Counsel,

Please see below for an updated list, which includes one further UTC witness's availability (Patterson).

Regards,

KATHY PAPPAS  
Associate  
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**From:** Pappas, Katherine  
**Sent:** Tuesday, October 15, 2024 2:51 PM  
**To:** McDermott, Sydney <[Smcdermott@mwe.com](mailto:Smcdermott@mwe.com)>; Dykhuis, Art <[Adykhuis@mwe.com](mailto:Adykhuis@mwe.com)>; Vallen, Jake <[Jvallen@mwe.com](mailto:Jvallen@mwe.com)>; Davies, Jonathan <[jdavies@cooley.com](mailto:jdavies@cooley.com)>; Minn, Robert <[rminn@cooley.com](mailto:rminn@cooley.com)>; Burrowbridge, Adam <[Aburrowbridge@mwe.com](mailto:Aburrowbridge@mwe.com)>; Carsten, Douglas <[Dcarsten@mwe.com](mailto:Dcarsten@mwe.com)>; [WJackson@goodwinlaw.com](mailto:WJackson@goodwinlaw.com); [mflynn@morrisnichols.com](mailto:mflynn@morrisnichols.com)  
**Cc:** z/Liquidia v UTC 308970-201 <[zLiquidiavUTC308970201@cooley.com](mailto:zLiquidiavUTC308970201@cooley.com)>; DG-ILD <[DG-ILD@goodwinlaw.com](mailto:DG-ILD@goodwinlaw.com)>; UTCvLiquidia-Del-23cv975 <[UTCvLiquidia-Del-23cv975@mwe.com](mailto:UTCvLiquidia-Del-23cv975@mwe.com)>  
**Subject:** RE: UTC v. Liquidia (23-975) - Deposition dates for witnesses

Counsel,

Following up regarding scheduling of depositions, please see below updated list for UTC witnesses, which includes dates previously offered.

Byrd 10/15 (completed)

Smith 10/22

Barton 10/25

Bunce 10/29

Maebius 10/31

Patterson 11/5

Peterson 11/6

Deng 11/12

Bottorff 11/12

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**Sent:** Tuesday, October 15, 2024 2:46 PM

**To:** Dykhuis, Art <[Adykhuis@mwe.com](mailto:Adykhuis@mwe.com)>; Vallen, Jake <[Jvallen@mwe.com](mailto:Jvallen@mwe.com)>; Davies, Jonathan <[jdavies@cooley.com](mailto:jdavies@cooley.com)>; Minn, Robert <[rminn@cooley.com](mailto:rminn@cooley.com)>; Burrowbridge, Adam <[Aburrowbridge@mwe.com](mailto:Aburrowbridge@mwe.com)>; Carsten, Douglas <[Dcarsten@mwe.com](mailto:Dcarsten@mwe.com)>; [WJackson@goodwinlaw.com](mailto:WJackson@goodwinlaw.com); Pappas, Katherine <[Kpappas@mwe.com](mailto:Kpappas@mwe.com)>; [mflynn@morrisonichols.com](mailto:mflynn@morrisonichols.com)

**Cc:** z/Liquidia v UTC 308970-201 <[zLiquidiavUTC308970201@cooley.com](mailto:zLiquidiavUTC308970201@cooley.com)>; DG-ILD <[DG-ILD@goodwinlaw.com](mailto:DG-ILD@goodwinlaw.com)>; UTCvLiquidia-Del-23cv975 <[UTCvLiquidia-Del-23cv975@mwe.com](mailto:UTCvLiquidia-Del-23cv975@mwe.com)>

**Subject:** RE: UTC v. Liquidia (23-975) - Deposition dates for witnesses

Counsel,

UTC's requests for "[a] complete copy of Liquidia's NDA, Liquidia's NDA Amendment, and any subsequent amendments or supplemental NDAs for Yutrepia"; "[a]ll correspondence with FDA relating to Liquidia's NDA and Liquidia's NDA Amendment, and any subsequent amendments or supplemental NDAs for Yutrepia," and "Liquidia's **current** regulatory tracking logs" were served in May. (Plaintiff's First Set of Requests for Production of Documents and Things – Request Nos. 1-3). Despite this request, Liquidia waited until October 4<sup>th</sup> to produce updated Regulatory Logs. Prior to that date, Liquidia withheld these updated logs for no reason while assuring UTC that Liquidia had produced all relevant regulatory documents. When UTC was finally able to review the current logs, UTC discovered that Liquidia has withheld regulatory submissions without explanation and despite its previous representations to the contrary. UTC informed Liquidia that its production was deficient last Thursday (October 10<sup>th</sup>). UTC emphasized that the regulatory documents are necessary to take the impending deposition of Dr. Rajeev Saggars—a deponent Liquidia refused to offer at a later date, despite UTC's repeated observations surrounding Liquidia's deficient productions. Last Friday and Saturday (October 11<sup>th</sup> and 12<sup>th</sup>) Liquidia produced some additional regulatory documents, but still failed to produce all of them. For many regulatory submissions, Liquidia provided only the filing receipt and cover letter, withholding the

submissions themselves. Despite Liquidia's continued assurance that all regulatory documents have been produced, Liquidia has not lived up to its word.

UTC will not identify every line of Liquidia's logs that Liquidia has failed to produce. But, by way of example, in a case that started because Liquidia filed an Amendment to its NDA seeking to add PH-ILD as an indication, Liquidia still has not produced that Amendment. Nevertheless, Liquidia has charged forward with Dr. Rajeev Saggar's deposition date, refusing to provide a date that post-dates all regulatory productions. Notwithstanding, UTC plans to proceed with the deposition as scheduled. However, due to Liquidia's repeated failure to comply with its obligations to produce the documents needed to gather relevant information from Dr. Rajeev Saggar, this serves as a reminder that UTC will hold the deposition open.

SYDNEY McDERMOTT (SHE/HER/HERS)

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---

**From:** Dykhuis, Art <[Adykhuis@mwe.com](mailto:Adykhuis@mwe.com)>

**Sent:** Friday, October 11, 2024 11:53 PM

**To:** Vallen, Jake <[Jvallen@mwe.com](mailto:Jvallen@mwe.com)>; Davies, Jonathan <[jdavies@cooley.com](mailto:jdavies@cooley.com)>; Minn, Robert <[rminn@cooley.com](mailto:rminn@cooley.com)>; Burrowbridge, Adam <[Aburrowbridge@mwe.com](mailto:Aburrowbridge@mwe.com)>; Carsten, Douglas <[Dcarsten@mwe.com](mailto:Dcarsten@mwe.com)>;

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**Subject:** Re: UTC v. Liquidia (23-975) - Deposition dates for witnesses

Jon – following up on the Saggar deposition, we will proceed next week on the date you offered. We intend to hold the deposition open and reserve the right to seek an additional deposition date in view of Liquidia's deficient document production – not just because, but especially because, we only earlier today received a document production that supposedly provides the documents Liquidia previously withheld. But at this point we do not know if it actually contains all of the missing documents identified below (let alone any others that, like these, Liquidia has withheld without explanation). The deposition will proceed at the address below. We will provide court reporter info when we have it, but if you have any initial requests, let us know and we can pass them on.

Spencer Fane LLP  
2415 E Camelback Rd Suite 600  
Phoenix, AZ 85016

In addition, Greg Bottorff is available on 11/12 in Raleigh.

ART DYKHUIS  
Partner

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---

**From:** Vallen, Jake <[jvallen@mwe.com](mailto:jvallen@mwe.com)>

**Date:** Friday, October 11, 2024 at 9:17 AM

**To:** Davies, Jonathan <[jdavies@cooley.com](mailto:jdavies@cooley.com)>, Minn, Robert <[rminn@cooley.com](mailto:rminn@cooley.com)>, Dykhuis, Art <[Adykhuis@mwe.com](mailto:Adykhuis@mwe.com)>, Burrowbridge, Adam <[Aburrowbridge@mwe.com](mailto:Aburrowbridge@mwe.com)>, Carsten, Douglas <[Dcarsten@mwe.com](mailto:Dcarsten@mwe.com)>, [WJackson@goodwinlaw.com](mailto:WJackson@goodwinlaw.com) <[WJackson@goodwinlaw.com](mailto:WJackson@goodwinlaw.com)>, Pappas, Katherine <[Kpappas@mwe.com](mailto:Kpappas@mwe.com)>, [mflynn@morrisnichols.com](mailto:mflynn@morrisnichols.com) <[mflynn@morrisnichols.com](mailto:mflynn@morrisnichols.com)>

**Cc:** z/Liquidia v UTC 308970-201 <[zLiquidiavUTC308970201@cooley.com](mailto:zLiquidiavUTC308970201@cooley.com)>, DG-ILD <[DG-ILD@goodwinlaw.com](mailto:DG-ILD@goodwinlaw.com)>, UTCvLiquidia-Del-23cv975 <[UTCvLiquidia-Del-23cv975@mwe.com](mailto:UTCvLiquidia-Del-23cv975@mwe.com)>

**Subject:** RE: UTC v. Liquidia (23-975) - Deposition dates for witnesses

Jon,

As you know, our requests for Liquidia's NDA, NDA amendment, FDA correspondence, and regulatory tracking logs were served in May. Liquidia withheld the regulatory logs for no reason and only produced them last Friday. Upon review of those logs, it appears that Liquidia also withheld regulatory materials despite Liquidia's previous representations to the contrary. We understand you will produce those materials, but we cannot meaningfully assess Liquidia's request to confirm Dr. Saggar's deposition date until the missing documents have been produced.

We look forward to receiving Liquidia's production today.

Thanks,  
Jake

JAKE B. VALLEN  
Associate

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---

**From:** Davies, Jonathan <[jdavies@cooley.com](mailto:jdavies@cooley.com)>

**Sent:** Thursday, October 10, 2024 9:03 PM

**To:** Vallen, Jake <[jvallen@mwe.com](mailto:jvallen@mwe.com)>; Dykhuis, Art <[Adykhuis@mwe.com](mailto:Adykhuis@mwe.com)>; Burrowbridge, Adam <[Aburrowbridge@mwe.com](mailto:Aburrowbridge@mwe.com)>; Carsten, Douglas <[Dcarsten@mwe.com](mailto:Dcarsten@mwe.com)>; [WJackson@goodwinlaw.com](mailto:WJackson@goodwinlaw.com); Pappas, Katherine <[Kpappas@mwe.com](mailto:Kpappas@mwe.com)>; [mflynn@morrisnichols.com](mailto:mflynn@morrisnichols.com)

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**Subject:** Re: UTC v. Liquidia (23-975) - Deposition dates for witnesses

[ External Email ]

Jake,

Dr. Saggar's deposition date was offered nearly three weeks ago. We are investigating your inquiries regarding approximately 15 entries on the regulatory tracker, and anticipate producing any additional regulatory communications tomorrow. Confirm you will proceed on the 16th and provide the requested information.

Thanks,  
Jon

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**From:** Vallen, Jake <[Jvallen@mwe.com](mailto:Jvallen@mwe.com)>  
**Sent:** Thursday, October 10, 2024 8:39 PM  
**To:** Minn, Robert <[rminn@cooley.com](mailto:rminn@cooley.com)>; Dykhuis, Art <[Adykhuis@mwe.com](mailto:Adykhuis@mwe.com)>; Burrowbridge, Adam <[Aburrowbridge@mwe.com](mailto:Aburrowbridge@mwe.com)>; Carsten, Douglas <[Dcarsten@mwe.com](mailto:Dcarsten@mwe.com)>; [WJackson@goodwinlaw.com](mailto:WJackson@goodwinlaw.com) <[WJackson@goodwinlaw.com](mailto:WJackson@goodwinlaw.com)>; Pappas, Katherine <[Kpappas@mwe.com](mailto:Kpappas@mwe.com)>; [mflynn@morrisnichols.com](mailto:mflynn@morrisnichols.com) <[mflynn@morrisnichols.com](mailto:mflynn@morrisnichols.com)>  
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**Subject:** RE: UTC v. Liquidia (23-975) - Deposition dates for witnesses

**[External]**

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Counsel,

In response to Jon's email in a different thread, we have yet to confirm Dr. Saggar's deposition and, as emailed about earlier today, there appear to be missing documents from Liquidia's regulatory production. We would suggest looking into additional dates for Dr. Saggar. Regardless of when the deposition proceeds, we will identify a location in Phoenix and provide to Liquidia in due course and as soon as we can. And we'll provide the court reporter information in advance (when we have it).

Regarding Noah Byrd's deposition, the deposition will proceed at Brooks Pierce in Raleigh. Please assume a 9am start time for now.

In addition:

- We can accept the 10/23 date for Janet Tully.
- As previously offered, Peter Smith is available on 10/22.
- Dean Bunce is available on 10/29 in Raleigh.
- Steve Maebius is available on 10/31 in Washington, DC.
- Leigh Peterson is available on 11/6 in Raleigh.

Regards,  
Jake

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**From:** Minn, Robert <[rminn@cooley.com](mailto:rminn@cooley.com)>  
**Sent:** Thursday, October 10, 2024 12:14 PM  
**To:** Dykhuis, Art <[Adykhuis@mwe.com](mailto:Adykhuis@mwe.com)>; Vallen, Jake <[Jvallen@mwe.com](mailto:Jvallen@mwe.com)>; Burrowbridge, Adam <[Aburrowbridge@mwe.com](mailto:Aburrowbridge@mwe.com)>; Carsten, Douglas <[Dcarsten@mwe.com](mailto:Dcarsten@mwe.com)>; [WJackson@goodwinlaw.com](mailto:WJackson@goodwinlaw.com); Pappas, Katherine <[Kpappas@mwe.com](mailto:Kpappas@mwe.com)>; [mflynn@morrisnichols.com](mailto:mflynn@morrisnichols.com) <[mflynn@morrisnichols.com](mailto:mflynn@morrisnichols.com)>  
**Cc:** z/Liquidia v UTC 308970-201 <[zLiquidiavUTC308970201@cooley.com](mailto:zLiquidiavUTC308970201@cooley.com)>; DG-ILD <[DG-ILD@goodwinlaw.com](mailto:DG-ILD@goodwinlaw.com)>; UTCvLiquidia-Del-23cv975 <[UTCvLiquidia-Del-23cv975@mwe.com](mailto:UTCvLiquidia-Del-23cv975@mwe.com)>  
**Subject:** RE: UTC v. Liquidia (23-975) - Deposition dates for witnesses

**[ External Email ]**

Counsel,

Confirming that Liquidia will take Noah Byrd's deposition on Oct. 15 in Raleigh, NC. Please confirm the address and start time of Mr. Byrd's deposition as soon as possible.

Thank you.

Robert

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**From:** Dykhuis, Art <[Adykhuis@mwe.com](mailto:Adykhuis@mwe.com)>

**Sent:** Tuesday, October 8, 2024 8:48 PM

**To:** Minn, Robert <[rminn@cooley.com](mailto:rminn@cooley.com)>; Vallen, Jake <[Jvallen@mwe.com](mailto:Jvallen@mwe.com)>; Burrowbridge, Adam <[Aburrowbridge@mwe.com](mailto:Aburrowbridge@mwe.com)>; Carsten, Douglas <[Dcarsten@mwe.com](mailto:Dcarsten@mwe.com)>; [WJackson@goodwinlaw.com](mailto:WJackson@goodwinlaw.com); Pappas, Katherine <[Kpappas@mwe.com](mailto:Kpappas@mwe.com)>; [mflynn@morrisnichols.com](mailto:mflynn@morrisnichols.com)

**Cc:** DG-ILD <[DG-ILD@goodwinlaw.com](mailto:DG-ILD@goodwinlaw.com)>; z/Liquidia v UTC 308970-201 <[zLiquidiaUTC308970201@cooley.com](mailto:zLiquidiaUTC308970201@cooley.com)>; UTCvLiquidia-Del-23cv975 <[UTCvLiquidia-Del-23cv975@mwe.com](mailto:UTCvLiquidia-Del-23cv975@mwe.com)>

**Subject:** Re: UTC v. Liquidia (23-975) - Deposition dates for witnesses

**[External]**

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Counsel,

We'll get back to you regarding Ms. Tully and Dr. Saggar, and thank you regarding Mr. Kasetta. Regarding depositions of UTC witnesses, Noah Byrd is available on 10/15 in Raleigh and Peter Smith is available on 10/22 in Raleigh.

Thanks,

Art

ART DYKHUIS

Partner

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**From:** Minn, Robert <[rminn@cooley.com](mailto:rminn@cooley.com)>

**Date:** Tuesday, October 8, 2024 at 2:08 PM

**To:** Vallen, Jake <[Jvallen@mwe.com](mailto:Jvallen@mwe.com)>, Dykhuis, Art <[Adykhuis@mwe.com](mailto:Adykhuis@mwe.com)>, Burrowbridge, Adam <[Aburrowbridge@mwe.com](mailto:Aburrowbridge@mwe.com)>, Carsten, Douglas <[Dcarsten@mwe.com](mailto:Dcarsten@mwe.com)>, [WJackson@goodwinlaw.com](mailto:WJackson@goodwinlaw.com) <[WJackson@goodwinlaw.com](mailto:WJackson@goodwinlaw.com)>, Pappas, Katherine <[Kpappas@mwe.com](mailto:Kpappas@mwe.com)>, [mflynn@morrisnichols.com](mailto:mflynn@morrisnichols.com) <[mflynn@morrisnichols.com](mailto:mflynn@morrisnichols.com)>

**Cc:** DG-ILD <[DG-ILD@goodwinlaw.com](mailto:DG-ILD@goodwinlaw.com)>, z/Liquidia v UTC 308970-201 <[zLiquidiaUTC308970201@cooley.com](mailto:zLiquidiaUTC308970201@cooley.com)>, UTCvLiquidia-Del-23cv975 <[UTCvLiquidia-Del-23cv975@mwe.com](mailto:UTCvLiquidia-Del-23cv975@mwe.com)>

**Subject:** RE: UTC v. Liquidia (23-975) - Deposition dates for witnesses

**[ External Email ]**

Jake,

- Janet Tully was disclosed as knowledgeable regarding “Drug device interactions regarding Yutrepia™ including technical specifications concerning the Plastiape RS00 Model 8 dry powder inhaler.” See Liquidia’s Rule 26 Initial Disclosures; Liquidia’s Delaware Default Discovery Standard Paragraph 3 Disclosures.

Liquidia has produced ample documents allowing UTC to explore this topic, including Plastiape’s DMF and various related documents regarding Liquidia’s DPI (including documents from Plastiape), the ASCENT trial protocol, the investigator’s brochure for LIQ861, and interim results for the ASCENT trial. As one example demonstrative of Liquidia’s fulsome document production, searching for the term “Plastiape” across Liquidia’s document production yields 612 documents.

Liquidia does not anticipate producing additional documents related to Ms. Tully or regarding Ms. Tully’s area of expertise. Ms. Tully will be made available on October 23 in Raleigh, NC, as previously offered.

- Regarding Mike Kasetta, Liquidia is not withholding any documents and the prospective financial information that UTC has asked for is irrelevant, as explained multiple times in previous letters, emails, and meet-and-confers. Nevertheless, Liquidia is willing to offer Mr. Kasetta at a later date given the parties’ dispute and its pending resolution in front of the Court.
- Regarding Dr. Rajeev Saggar, Liquidia has already produced a fulsome set of documents related to “Regulatory submissions relating to Liquidia’s Amended New Drug Application (‘NDA’) No. 213005 regarding the addition of PH-ILD to the Yutrepia™ Label.” Liquidia has produced all communications and submissions to the FDA up to date and will continue to produce documents on a rolling basis. Dr. Saggar will be made available on October 16, in the Phoenix area, as previously offered.

Thank you.

Robert

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**From:** Vallen, Jake <[jvallen@mwe.com](mailto:jvallen@mwe.com)>  
**Sent:** Tuesday, October 8, 2024 7:56 AM  
**To:** Minn, Robert <[rminn@cooley.com](mailto:rminn@cooley.com)>; Pappas, Katherine <[Kpappas@mwe.com](mailto:Kpappas@mwe.com)>; Dykhuis, Art <[Adykhuis@mwe.com](mailto:Adykhuis@mwe.com)>; Carsten, Douglas <[Dcarsten@mwe.com](mailto:Dcarsten@mwe.com)>; [WJackson@goodwinlaw.com](mailto:WJackson@goodwinlaw.com); Burrowbridge, Adam <[Aburrowbridge@mwe.com](mailto:Aburrowbridge@mwe.com)>  
**Cc:** z/Liquidia v UTC 308970-201 <[zLiquidiavUTC308970201@cooley.com](mailto:zLiquidiavUTC308970201@cooley.com)>; DG-ILD <[DG-ILD@goodwinlaw.com](mailto:DG-ILD@goodwinlaw.com)>; UTCvLiquidia-Del-23cv975 <[UTCvLiquidia-Del-23cv975@mwe.com](mailto:UTCvLiquidia-Del-23cv975@mwe.com)>  
**Subject:** RE: UTC v. Liquidia (23-975) - Deposition dates for witnesses

**[External]**

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Robert,

As you are aware, Liquidia has been withholding financial documents from UTC for several months. Liquidia is forcing UTC to seek the Court's assistance to get documents it needs for commercial success and damages. Thus, UTC is unable to accept the proposed date for Mr. Kasetta. This situation is of Liquidia's making, not UTC's.

As to Ms. Tully, Liquidia has produced 5 custodial documents from her files. That seems unlikely to be the full scope of relevant materials she possesses. Please confirm when Liquidia will finish its production regarding Ms. Tully.

Lastly, as to Dr. Saggar, you only produced last Friday the regulatory logs that we asked for months ago. We are evaluating those files and Liquidia's regulatory production, and are unable to accept a deposition date for Dr. Saggar until confirming the sufficiency of the relevant document production. Relatedly, please confirm whether Liquidia has produced all regulatory/FDA submissions and FDA correspondence through the present day—as Liquidia represented on the meet-and-confer last week—and confirm whether Liquidia will continue to produce such files on a rolling basis to ensure its production remains up to date.

Regards,  
Jake

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Associate

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**From:** Minn, Robert <[rminn@cooley.com](mailto:rminn@cooley.com)>  
**Sent:** Monday, October 7, 2024 7:05 PM  
**To:** Pappas, Katherine <[kpappas@mwe.com](mailto:kpappas@mwe.com)>; Dykhuis, Art <[Adykhuis@mwe.com](mailto:Adykhuis@mwe.com)>; Carsten, Douglas <[Dcarsten@mwe.com](mailto:Dcarsten@mwe.com)>; WJackson@goodwinlaw.com; Burrowbridge, Adam <[Aburrowbridge@mwe.com](mailto:Aburrowbridge@mwe.com)>  
**Cc:** z/Liquidia v UTC 308970-201 <[zLiquidiavUTC308970201@cooley.com](mailto:zLiquidiavUTC308970201@cooley.com)>; DG-ILD <[DG-ILD@goodwinlaw.com](mailto:DG-ILD@goodwinlaw.com)>; UTCvLiquidia-Del-23cv975 <[UTCvLiquidia-Del-23cv975@mwe.com](mailto:UTCvLiquidia-Del-23cv975@mwe.com)>  
**Subject:** UTC v. Liquidia (23-975) - Deposition dates for witnesses

[ External Email ]

Counsel,

As you are aware, at least 17 days have passed since Liquidia offered, upon UTC's request, dates for Dr. Saggar's and Mr. Kasetta's depositions and nearly two weeks have passed since Ms. Tully was offered. UTC's delay in responding is disrespectful to these individuals, who have had to hold their calendars open. UTC has also hindered counsel's ability to schedule matters in other cases while it awaits UTC's response. Given the extended passage of time, UTC's delay, and the pending close of fact discovery, these witnesses will only be made available at the dates and locations previously identified. IF UTC does not intend to depose these individuals, please confirm immediately.

Best,  
Robert

**Robert Minn**  
Associate

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# EXHIBIT 11

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS	)
CORPORATION,	)
	)
Plaintiff	)
	) C.A. No. 23-975 (RGA) (SRF)
v.	)
	) [REDACTED]
LIQUIDIA TECHNOLOGIES, INC.,	)
	)
Defendant.	)

**PLAINTIFF'S AMENDED FIRST SUPPLEMENTAL RESPONSES AND OBJECTIONS  
TO DEFENDANT'S FIRST SET OF INTERROGATORIES TO PLAINTIFF (NOS. 1-6)**

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure, Plaintiff United Therapeutics Corporation (“UTC” or “Plaintiff”), by and through its undersigned counsel, hereby responds to Defendant Liquidia Technologies, Inc.’s (“Liquidia” or “Defendant”) First Set of Interrogatories (Nos. 1–6).<sup>1</sup>

**PRELIMINARY STATEMENT**

The following responses are made solely for the purpose of, and in relation to, this action. Each response is provided subject to all appropriate objections (including, without limitation, objections relating to competency, relevancy, propriety, proportionality, and admissibility) that would require the exclusion of any statement provided herein if that statement were made by a witness testifying in court. All such objections are reserved and may be interposed at the time of trial.

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<sup>1</sup> UTC previously offered supplemental responses to Liquidia’s Interrogatory Nos. 1, 2, 3, and 6 prior to the close of fact discovery on November 13, 2024. Consistent with the Court’s November 12, 2024 Memorandum Order (D.I. 193), UTC hereby serves supplemental responses to Liquidia’s Interrogatory Nos. 4 and 5.

extent it calls for information that can be obtained from others or public sources, is equally available to Liquidia and already indicated by documents that are publicly available, that Liquidia already possesses, or that have already been produced in this case.

Subject to its objections, UTC responds as follows:

UTC directs Liquidia to the following documents under Fed. R. Civ. P. 33(d): the '327 patent; UTC\_PH-ILD\_009419-UTC\_PH-ILD\_09771 (file history of '327 patent); Provisional Application No. 63/011,810 filed on April 17, 2020.

Discovery is in the early stages and additional documents produced by UTC may be relevant to this Interrogatory. To the extent appropriate, UTC may cite such documents pursuant to Fed. R. Civ. P. 33(d) in due course. To the extent appropriate, UTC also expects that the subject matter of this request may be addressed during expert discovery.

Discovery and UTC's investigation into facts relevant to this case is ongoing, and UTC expressly reserves the right to amend and/or supplement its answer to this Interrogatory as discovery and the case continues.

**FIRST SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 5 (11/19/2024):**

Subject to and without waiving the foregoing General and Specific Objections, UTC provides the following chart identifying, for each Asserted Claim of the '327 patent on a claim-by-claim basis, where support may be found regarding UTC's claim of priority to U.S. Provisional Application No. 63/011,810. For the avoidance of doubt, each Asserted Claim is entitled to claim the benefit of Provisional Application No. 63/011,810 filed on April 17, 2020. A POSA would understand the disclosures and claims of Provisional Application No. 63/011,810 to describe and enable each and every limitation of every Asserted Claim of the '327 patent in light of the POSA's knowledge and the available prior art as of April 17, 2020. The following disclosures are

exemplary and are offered without waiver of UTC's right to rely on additional disclosures or references, including the knowledge of a POSA, during expert discovery and through trial.

Asserted '327 Patent Claim	Support Found in Provisional Application No. 63/011,810
<p><b>1.</b> A method of improving exercise capacity in a patient having pulmonary hypertension associated with interstitial lung disease, comprising</p>	<p>[0001] ("The present application generally relates to treatment of interstitial lung disease and pulmonary fibrosis with prostacyclins and more particularly, treprostinil, a prodrug, salt, or ester thereof.").</p> <p>[0005] ("In one aspect, a method of increasing forced vital capacity (FVC) in a subject suffering from ILD is provided, comprising administering to the subject treprostinil, a prodrug, salt, or ester thereof.").</p> <p>[00015] ("FIG. 1 shows a Kaplan-Meier plot of time to exacerbation of underlying lung disease over a 16-week period of treprostinil treatment.").</p> <p><b>Figure 1</b></p> <p>[0029] ("The term 'treatment' or 'treating' means administering a compound disclosed herein for the purpose of (i) delaying the onset of a disease, that is, causing the clinical symptoms of the disease not to develop or delaying the development thereof; (ii) inhibiting the disease, that is, arresting the development of clinical symptoms; and/or (iii) relieving the disease, that is, causing the regression of clinical symptoms or the severity thereof.").</p> <p>[0060] ("In preferred embodiments, treprostinil is administered via inhalation. Inhaled compositions comprising treprostinil may include sprays, aerosols, and dry powder compositions. Said compositions may include a variety of excipients. Inhalable compositions administered may include any of those described in U.S. Patent No. 9,339,507 (including the commercial product Tyvaso® (treprostinil) Inhalation Solution), PCT/US2017/031301 and PCT/US2013/072647, the entire disclosures of which are hereby incorporated by reference.<sup>7</sup>"</p> <p>[0080] ("An exacerbation of underlying lung disease is defined as an acute, clinically significant, respiratory deterioration characterized by evidence of new widespread alveolar abnormality (Collard et al., 2016). The present example shows that treatment with inhaled</p>

<sup>7</sup> A POSA would consider the contents of U.S. Patent No. 9,339,507, PCT/US2017/031301, and PCT/US2013/072647 in their entirety.

Asserted '327 Patent Claim	Support Found in Provisional Application No. 63/011,810
	<p>treprostinil resulted in significantly fewer exacerbations of underlying lung disease in patients.”).</p> <p>[0081] (“Subjects having underlying lung disease were treated with inhaled treprostinil over 16 weeks. Subjects initiated inhaled treprostinil or placebo at a dose of 3 breaths (18 mcg) 4 times daily (during waking hours). Study drug doses were maximized throughout the study. Dose escalations (additional 1 breath 4 times daily) could occur up to every 3 days with a target dosing regimen of 9 breaths (54 mcg) 4 times daily and a maximum dose of 12 breaths (72 mcg) 4 times daily, as clinically tolerated. Subjects were assessed during Screening and Baseline to determine eligibility for the study. Once eligible, 5 Treatment Phase visits to the clinic were required at Week 4, Week 8, Week 12, Week 15, and Week 16 (final study visit). An Early Termination (ET) Visit was conducted for subjects who discontinued prior to Week 16; all assessments planned for the final Week 16 Visit were conducted during the ET Visit, if applicable. Subjects were contacted at least weekly by telephone or email to assess tolerance to study drug, adverse events (AEs), and changes to concomitant medications.”).</p> <p>[0082] (“Efficacy assessments consisted of 6MWD, plasma NT-proBNP concentration, and time to clinical worsening. Exploratory endpoints included SGRQ, change in DSP, time to exacerbation of underlying disease, and pulmonary function tests. Safety assessments consisted of the development of AEs, vital signs, clinical laboratory parameters, ECG parameters, hospitalizations due to cardiopulmonary indications, exacerbations of underlying lung disease, and oxygenation.”).</p> <p>[0083] (“Treatment resulted in significantly fewer exacerbations of underlying lung disease over the 16-week treatment period (26.4% in Inhaled Treprostinil group and 38.7% in placebo group; p=0.018) and decreased risk of an exacerbation of underlying lung disease (hazard ratio 0.66 or 34% reduction in risk) as shown in FIG. 1.”).</p> <p>[0084] (“In addition, the following FVC suggestive data was obtained from this study. Among patients treated with inhaled treprostinil, overall results from intent to treat group were:</p> <p>Overall ITT</p> <p>28.47 mL and 44.40 mL in FVC at Weeks 8 and 16</p>

Asserted '327 Patent Claim	Support Found in Provisional Application No. 63/011,810
	<p>Percent predicted FVC at Week 8 (1.79%; p=0.0139) and Week 16 (1.80%; p=0.0277).</p> <p>Subset IIP etiology:</p> <p>46.48 mL and 108.18 mL (p=0.0229) at Weeks 8 and 16</p> <p>Percent predicted FVC at Week 8 (1.95%, p=0.0373) and Week 16 (2.88%; p=0.0096)</p> <p>Subset IPF etiology:</p> <p>84.52 mL and 168.52 mL (p=0.0108) at Weeks 8 and 16</p> <p>Percent predicted FVC at Week 8 (2.54%; p=0.0380) and Week 16 (3.50%; p=0.0147)</p> <p>Nintedanib: IPF - 109 mL (3.2% predicted) at 52 weeks</p> <p>Pirfenidone: IPF - 153-193 mL at 52 weeks</p> <p>Placebo corrected, rate of decline (not improvements)</p> <p>In comparison to the known treatments for ILD (nintedanib and pirfenidone) shown above, inhaled treprostinil achieves comparable effects with shorter treatment duration.”).</p> <p>[0085] (“Pulmonary function testing was initially conducted as a safety assessment (Safety Population) during the study. The results indicated that although most PFT parameters remained stable for subjects in the study, a notable improvement in FVC (% predicted) was observed at Week 16 in the inhaled treprostinil group (median improvement of 1.0% compared to a 1.0% reduction in the placebo group). As a result, post hoc MMRM analyses of FVC data were performed for the ITT Population and are presented in Table 1 (ITT Population), Table 2 (by PH ILD Etiology of IIP) and Table 3 (for subjects with IPF), shown below.”).</p> <p><b>Table 1: Analysis of FVC Data Using Mixed Model Repeated Measurement – ITT Population</b></p>

Asserted '327 Patent Claim		Support Found in Provisional Application No. 63/011,810						
Visit	Treatment	N	LS Mean	Contrast	Estimated Difference	95% CI	p-value	
<b>FVC (mL)</b>								
Week 8	Inhaled treprostinil	142	5.49	Inhaled treprostinil - Placebo	28.47	-30.81, 87.74	0.3453	
	Placebo	141	-22.98					
Week 16	Inhaled treprostinil	130	9.77	Inhaled treprostinil - Placebo	44.40	-25.25, 114.05	0.2106	
	Placebo	126	-34.63					
<b>FVC (% predicted)</b>								
Week 8	Inhaled treprostinil	142	0.77	Inhaled treprostinil - Placebo	1.79	0.37, 3.21	0.0139	
	Placebo	141	-1.02					
Week 16	Inhaled treprostinil	130	1.07	Inhaled treprostinil - Placebo	1.80	0.20, 3.39	0.0277	
	Placebo	126	-0.72					

Abbreviations: CI, confidence interval; FVC, forced vital capacity; ITT, Intent-to-Treat; LS, least square; MMRM, mixed model repeated measurement  
LSMean, p-values, estimated difference, and associated 95% CI were from the MMRM with the change from baseline in FVC/% predicted FVC as the dependent variable; treatment, week, treatment by week interaction as the fixed effects; baseline FVC/% predicted FVC as the covariate; and subject as the random effect. An unstructured variance/covariance structure shared across treatment groups was used to model the within-subject errors.

**Table 2: Analysis of FVC Data Using Mixed Model Repeated Measurement for PH-ILD Etiology of IIP – ITT Population**

Visit	Treatment	N	LS Mean	Contrast	Estimated Difference	95% CI	p-value
<b>PH-ILD Etiology: IIP</b>							
<b>FVC (mL)</b>							
Week 8	Inhaled treprostinil	58	9.27	Inhaled treprostinil - Placebo	46.48	-32.55, 125.51	0.2467
	Placebo	71	-37.21				
Week 16	Inhaled treprostinil	52	22.16	Inhaled treprostinil - Placebo	108.18	15.25, 201.10	0.0229
	Placebo	63	-86.02				
<b>FVC (% predicted)</b>							
Week 8	Inhaled treprostinil	58	0.92	Inhaled treprostinil - Placebo	1.95	0.12, 3.79	0.0373
	Placebo	71	-1.03				
Week 16	Inhaled treprostinil	52	1.66	Inhaled treprostinil - Placebo	2.88	0.72, 5.05	0.0096
	Placebo	63	-1.23				

Abbreviations: CI, confidence interval; CPFE, combined pulmonary fibrosis and emphysema; CTD, connective tissue disease; FVC, forced vital capacity; ILD, interstitial lung disease; IIP, idiopathic interstitial pneumonia; ITT, Intent-to-Treat; LS, least square; MMRM, mixed model repeated measurement  
LSMean, p-values, estimated difference, and associated 95% CI were from the MMRM with the change from baseline in FVC/% predicted FVC as the dependent variable; treatment, week, treatment by week interaction as the fixed effects; baseline FVC/% predicted FVC as the covariate; and subject as the random effect. An unstructured variance/covariance structure shared across treatment groups was used to model the within-subject errors.

**Table 3: Analysis of FVC Data Using Mixed Model Repeated Measurement for Subjects with IPF - ITT for IIP Subjects**

Asserted '327 Patent Claim	Support Found in Provisional Application No. 63/011,810																																																																																								
	<table border="1"> <thead> <tr> <th data-bbox="527 280 567 302">IPF</th><th data-bbox="527 302 567 323"></th><th data-bbox="527 323 567 344"></th><th data-bbox="527 344 567 365"></th><th data-bbox="527 365 567 386"></th><th data-bbox="527 386 567 407"></th><th data-bbox="527 407 567 428"></th><th data-bbox="527 428 567 449"></th></tr> </thead> <tbody> <tr> <td data-bbox="527 302 567 323">FVC (mL)</td><td data-bbox="527 323 567 344"></td><td data-bbox="527 344 567 365"></td><td data-bbox="527 365 567 386"></td><td data-bbox="527 386 567 407"></td><td data-bbox="527 407 567 428"></td><td data-bbox="527 428 567 449"></td><td data-bbox="527 449 567 470"></td></tr> <tr> <td data-bbox="527 323 567 344">Week 8</td><td data-bbox="527 344 567 365">Inhaled treprostinil</td><td data-bbox="527 365 567 386">31</td><td data-bbox="527 386 567 407">41.69</td><td data-bbox="527 407 567 428">Inhaled treprostinil - Placebo</td><td data-bbox="527 428 567 449">84.522</td><td data-bbox="527 449 567 470">-20.409, 189.454</td><td data-bbox="527 470 567 492">0.1128</td></tr> <tr> <td data-bbox="527 344 567 365"></td><td data-bbox="527 365 567 386">Placebo</td><td data-bbox="527 386 567 407">47</td><td data-bbox="527 407 567 428">-42.83</td><td data-bbox="527 428 567 449"></td><td data-bbox="527 449 567 470"></td><td data-bbox="527 470 567 492"></td><td data-bbox="527 492 567 513"></td></tr> <tr> <td data-bbox="527 365 567 386">Week 16</td><td data-bbox="527 386 567 407">Inhaled treprostinil</td><td data-bbox="527 407 567 428">28</td><td data-bbox="527 428 567 449">38.24</td><td data-bbox="527 449 567 470">Inhaled treprostinil - Placebo</td><td data-bbox="527 470 567 492">168.524</td><td data-bbox="527 492 567 513">40.078, 296.970</td><td data-bbox="527 513 567 534">0.0108</td></tr> <tr> <td data-bbox="527 386 567 407"></td><td data-bbox="527 407 567 428">Placebo</td><td data-bbox="527 428 567 449">42</td><td data-bbox="527 449 567 470">-130.3</td><td data-bbox="527 470 567 492"></td><td data-bbox="527 492 567 513"></td><td data-bbox="527 513 567 534"></td><td data-bbox="527 534 567 555"></td></tr> <tr> <td data-bbox="527 470 567 492">FVC (% predicted)</td><td data-bbox="527 492 567 513"></td><td data-bbox="527 513 567 534"></td><td data-bbox="527 534 567 555"></td><td data-bbox="527 555 567 576"></td><td data-bbox="527 576 567 597"></td><td data-bbox="527 597 567 618"></td><td data-bbox="527 618 567 639"></td></tr> <tr> <td data-bbox="527 492 567 513">Week 8</td><td data-bbox="527 513 567 534">Inhaled treprostinil</td><td data-bbox="527 534 567 555">31</td><td data-bbox="527 555 567 576">1.60</td><td data-bbox="527 576 567 597">Inhaled treprostinil - Placebo</td><td data-bbox="527 597 567 618">2.543</td><td data-bbox="527 618 567 639">0.145, 4.941</td><td data-bbox="527 639 567 661">0.0380</td></tr> <tr> <td data-bbox="527 513 567 534"></td><td data-bbox="527 534 567 555">Placebo</td><td data-bbox="527 555 567 576">47</td><td data-bbox="527 576 567 597">-0.94</td><td data-bbox="527 597 567 618"></td><td data-bbox="527 618 567 639"></td><td data-bbox="527 639 567 661"></td><td data-bbox="527 661 567 682"></td></tr> <tr> <td data-bbox="527 534 567 555">Week 16</td><td data-bbox="527 555 567 576">Inhaled treprostinil</td><td data-bbox="527 576 567 597">28</td><td data-bbox="527 597 567 618">1.62</td><td data-bbox="527 618 567 639">Inhaled treprostinil - Placebo</td><td data-bbox="527 639 567 661">3.504</td><td data-bbox="527 661 567 682">0.712, 6.295</td><td data-bbox="527 682 567 703">0.0147</td></tr> <tr> <td data-bbox="527 555 567 576"></td><td data-bbox="527 576 567 597">Placebo</td><td data-bbox="527 597 567 618">42</td><td data-bbox="527 618 567 639">-1.88</td><td data-bbox="527 639 567 661"></td><td data-bbox="527 661 567 682"></td><td data-bbox="527 682 567 703"></td><td data-bbox="527 703 567 724"></td></tr> </tbody> </table>	IPF								FVC (mL)								Week 8	Inhaled treprostinil	31	41.69	Inhaled treprostinil - Placebo	84.522	-20.409, 189.454	0.1128		Placebo	47	-42.83					Week 16	Inhaled treprostinil	28	38.24	Inhaled treprostinil - Placebo	168.524	40.078, 296.970	0.0108		Placebo	42	-130.3					FVC (% predicted)								Week 8	Inhaled treprostinil	31	1.60	Inhaled treprostinil - Placebo	2.543	0.145, 4.941	0.0380		Placebo	47	-0.94					Week 16	Inhaled treprostinil	28	1.62	Inhaled treprostinil - Placebo	3.504	0.712, 6.295	0.0147		Placebo	42	-1.88				
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<p>[0088] (“Further analysis of FVC for subjects with an IPF etiology (using only the IIP subjects in the ITT Population), showed that treatment with inhaled treprostinil resulted in improvements of 84.52 mL and 168.52 mL (p=0.0108) compared to placebo at Weeks 8 and 16, respectively. The between group differences for% predicted FVC were statistically significant at Week 8 (2.54%; p=0.0380) and Week 16 (3.50%; p=0.0147).”).</p>																																																																																									
<p><b>Claim 1</b> (“A method of treating interstitial lung disease (ILD) or pulmonary fibrosis in a subject in need, comprising administering to the subject a therapeutically effective amount of treprostinil, a prodrug, salt, or ester thereof.”).</p>																																																																																									
<p><b>Claim 2</b> (“A method of reducing pulmonary function decline in a subject with interstitial lung disease (ILD) or pulmonary fibrosis,</p>																																																																																									

Asserted '327 Patent Claim	Support Found in Provisional Application No. 63/011,810
	<p>comprising administering to the subject treprostinil, a prodrug, salt, or ester thereof.”).</p> <p><b>Claim 3</b> (“A method of increasing forced vital capacity (FVC) in a subject suffering from ILD or pulmonary fibrosis, comprising administering to the subject treprostinil, a prodrug, salt, or ester thereof.”).</p> <p><b>Claim 4</b> (“The method of any one of claims 1-3, wherein the ILD comprises one or more of idiopathic pulmonary fibrosis (IPF), desquamative interstitial pneumonia (DIP), acute interstitial pneumonia (AIP), nonspecific interstitial pneumonia (NSIP), respiratory bronchiolitis-associated interstitial lung disease (RB-ILD), cryptogenic organizing pneumonia (COP), lymphoid interstitial pneumonia (LIP), sarcoidosis, rheumatoid arthritis, systemic lupus erythematosus, systemic sclerosis, polymyositis, dermatomyositis, antisynthetase syndrome, silicosis, asbestosis, occupational lung disease, chronic hypersensitivity pneumonitis, idiopathic interstitial pneumonia (IIP), an autoimmune ILD, lymphangioleiomyomatosis (LAM), Langerhan’s cell histiocytosis (LCH), drug associated ILD, vasculitis, granulomatosis, and berylliosis.”).</p> <p><b>Claim 5</b> (“The method of claim 4, wherein the ILD comprises IPF.”).</p> <p><b>Claim 6</b> (“The method of any one of claims 1-5, wherein the ILD comprises systemic sclerosis associated interstitial lung disease (SSc-ILD.”).</p> <p><b>Claim 7</b> (“The method of any one of claims 1-6, wherein the ILD was induced from antibiotics, chemotherapy, antiarrhythmic agents, coronavirus disease 2019, atypical pneumonia, pneumocystis pneumonia, tuberculosis (TB), <i>chlamydia trachomatis</i>, respiratory syncytial virus, or lymphangitic carcinomatosis.”).</p> <p><b>Claim 8</b> (“The method of any one of claims 1-7, wherein the subject has one or more of surfactant-protein-B deficiency, surfactant-protein-C deficiency, ABCA3-deficiency, brain lung thyroid syndrome, congenital pulmonary alveolar proteinosis, alveolar capillary dysplasia, mutations in telomerase reverse transcriptase, mutations in telomerase RNA component, mutations in the regulator of telomere elongation helicase 1, and mutations in poly(A)-specific ribonuclease.”).</p>

Asserted '327 Patent Claim	Support Found in Provisional Application No. 63/011,810
	<p><b>Claim 9</b> (“The method of any one of claims 1-8, wherein the subject has one or more symptoms of shortness of breath, fatigue, weight loss, dry cough, chest pain, and lung hemorrhage.”).</p> <p><b>Claim 10</b> (“The method of claim 9, wherein after administration the symptom is improved by about 5%, about 10%, about 15%, about 20%, about 25%, about 30%, about 35%, about 40%, about 45%, about 50%, about 55%, about 60%, about 65%, about 70%, about 75%, about 80%, about 85%, about 90%, about 95%, or about 100%, as measured by a medically-recognized technique.”).</p> <p><b>Claim 11</b> (“The method of claim 10, wherein the medically-recognized technique comprises one or more of Modified Medical Research Council (MMRC) Dyspnoea Scale, Modified Borg Dyspnoea Scale (0-10), Chalder Fatigue Scale, weight measurement scale, visual analogue scale (VAS) for cough, King's Brief Interstitial Lung Disease Questionnaire, Leicester Cough Questionnaire (LCQ), computed tomography (CT) scan, X-ray, multiple magnetic resonance imaging (MRI), pulmonary function testing (PFT), spirometry, lung volumes, maximal respiratory pressure, diffusing capacity, oxygen desaturation, and arterial blood gas evaluation.”).</p> <p><b>Claim 12</b> (“The method of any one of claims 1-11, wherein treprostinil, a prodrug, salt, or ester thereof is administered in a pharmaceutical composition comprising treprostinil, a prodrug, salt, or ester thereof and a pharmaceutically acceptable carrier or excipient.”).</p> <p><b>Claim 13</b> (“The method of claim any one of claims 1-12, wherein the administration comprises at least one of oral, inhalation, subcutaneous, nasal, intravenous, intramuscular, sublingual, buccal, rectal, vaginal, and transdermal administration.”).</p> <p><b>Claim 14</b> (“The method of any one of claims 1-13, wherein the administration comprises inhalation.”).</p> <p><b>Claim 15</b> (“The method of any one of claims 1-14, wherein a single inhalation administration event comprises from 1 to 20 breaths.”).</p> <p><b>Claim 19</b> (“The method of any one of claims 1-18, wherein administration is once, twice, thrice, four times, five times, or six times per day.”).</p> <p><b>Claim 20</b> (“The method of any one of claims 1-19, wherein administration is for a period selected from the group consisting of about 1 day, about 1 day to about 3 days, about 3 days to about 6 days,</p>

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	<p>about 6 days to about 9 days, about 9 days to about 12 days, about 12 days to about 15 days, about 15 days to about 18 days, about 18 days to about 21 days, about 21 days to about 24 days, about 24 days to about 27 days, about 27 days to about 30 days, or about greater than 30 days.”).</p> <p><b>Claim 21</b> (“The method of any one of claims 1-20, wherein the subject is a human.”).</p> <p><b>Claim 22</b> (“The method of any one of claims 1-21, wherein the method results in an increased FVC compared to the FVC at the start of or prior to the start of administration.”).</p> <p><b>Claim 23</b> (“The method of claim 22, wherein the administration results in an increased FVC at sixteen weeks after the start of administration compared to the FVC at the start of or prior to the start of administration.”).</p> <p><b>Claim 24</b> (“The method of any one of claims 22-23, wherein the increase in FVC is at least 20%.”).</p> <p><b>Claim 25</b> (“The method of claim 24, wherein the increase in FVC is at least 75%.”).</p> <p>A POSA would read each and every one of these disclosures in light of the POSA’s understanding of the relevant art. UTC’s investigation into the facts relevant to this issue is ongoing and expert discovery is in its early stages. UTC thus offers the above support without waiver of its right to rely on the knowledge of a POSA to further establish priority to Provisional Application No. 63/011,810.</p>
administering by inhalation to the patient having pulmonary hypertension associated with interstitial lung disease	<p>[0026] (“Treprostinil is used for the treatment of pulmonary arterial hypertension.”).</p> <p>[0060] (“In preferred embodiments, treprostinil is administered via inhalation. Inhaled compositions comprising treprostinil may include sprays, aerosols, and dry powder compositions. Said compositions may include a variety of excipients. Inhalable compositions administered may include any of those described in U.S. Patent No. 9,339,507 (including the commercial product Tyvaso® (treprostinil) Inhalation Solution), PCT/US2017/031301 and PCT/US2013/072647, the entire disclosures of which are hereby incorporated by reference.”).<sup>8</sup></p>

<sup>8</sup> A POSA would consider the contents of U.S. Patent No. 9,339,507, PCT/US2017/031301, and PCT/US2013/072647 in their entirety.

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	<p>[0081] (“Subjects having underlying lung disease were treated with inhaled treprostinil over 16 weeks. Subjects initiated inhaled treprostinil or placebo at a dose of 3 breaths (18 mcg) 4 times daily (during waking hours). Study drug doses were maximized throughout the study. Dose escalations (additional 1 breath 4 times daily) could occur up to every 3 days with a target dosing regimen of 9 breaths (54 mcg) 4 times daily and a maximum dose of 12 breaths (72 mcg) 4 times daily, as clinically tolerated. Subjects were assessed during Screening and Baseline to determine eligibility for the study. Once eligible, 5 Treatment Phase visits to the clinic were required at Week 4, Week 8, Week 12, Week 15, and Week 16 (final study visit). An Early Termination (ET) Visit was conducted for subjects who discontinued prior to Week 16; all assessments planned for the final Week 16 Visit were conducted during the ET Visit, if applicable. Subjects were contacted at least weekly by telephone or email to assess tolerance to study drug, adverse events (AEs ), and changes to concomitant medications.”).</p> <p>A POSA would read each and every one of these disclosures in light of the POSA’s understanding of the relevant art. UTC’s investigation into the facts relevant to this issue is ongoing and expert discovery is in its early stages. UTC thus offers the above support without waiver of its right to rely on the knowledge of a POSA to further establish priority to Provisional Application No. 63/011,810.</p>
an effective amount of at least 15 micrograms up to a maximum tolerated dose of treprostinil or a pharmaceutically acceptable salt thereof	<p>[0081] (“Subjects having underlying lung disease were treated with inhaled treprostinil over 16 weeks. Subjects initiated inhaled treprostinil or placebo at a dose of 3 breaths (18 mcg) 4 times daily (during waking hours). Study drug doses were maximized throughout the study. Dose escalations (additional 1 breath 4 times daily) could occur up to every 3 days with a target dosing regimen of 9 breaths (54 mcg) 4 times daily and a maximum dose of 12 breaths (72 mcg) 4 times daily, as clinically tolerated.”).</p> <p>A POSA would read each and every one of these disclosures in light of the POSA’s understanding of the relevant art. UTC’s investigation into the facts relevant to this issue is ongoing and expert discovery is in its early stages. UTC thus offers the above support without waiver of its right to rely on the knowledge of a POSA to further establish priority to Provisional Application No. 63/011,810.</p>
in a single administration event that comprises at	<p>[0081] (“Subjects having underlying lung disease were treated with inhaled treprostinil over 16 weeks. Subjects initiated inhaled treprostinil or placebo at a dose of 3 breaths (18 mcg) 4 times daily (during waking hours). Study drug doses were maximized throughout</p>

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least 6 micrograms per breath.	<p>the study. Dose escalations (additional 1 breath 4 times daily) could occur up to every 3 days with a target dosing regimen of 9 breaths (54 mcg) 4 times daily and a maximum dose of 12 breaths (72 mcg) 4 times daily, as clinically tolerated.”).</p> <p>A POSA would read each and every one of these disclosures in light of the POSA’s understanding of the relevant art. UTC’s investigation into the facts relevant to this issue is ongoing and expert discovery is in its early stages. UTC thus offers the above support without waiver of its right to rely on the knowledge of a POSA to further establish priority to Provisional Application No. 63/011,810.</p>
<p><b>2.</b> The method of claim 1, wherein said administering provides a statistically significant increase of a 6 minutes walk distance in the patient after 8 weeks, 12 weeks, or 16 weeks of the administering.</p>	<p>The disclosures cited <i>supra</i>, claim 1.</p> <p>[0080] (“An exacerbation of underlying lung disease is defined as an acute, clinically significant, respiratory deterioration characterized by evidence of new widespread alveolar abnormality (Collard et al., 2016). The present example shows that treatment with inhaled treprostinil resulted in significantly fewer exacerbations of underlying lung disease in patients.”).</p> <p>[0081] (“Subjects having underlying lung disease were treated with inhaled treprostinil over 16 weeks. Subjects initiated inhaled treprostinil or placebo at a dose of 3 breaths (18 mcg) 4 times daily (during waking hours). Study drug doses were maximized throughout the study. Dose escalations (additional 1 breath 4 times daily) could occur up to every 3 days with a target dosing regimen of 9 breaths (54 mcg) 4 times daily and a maximum dose of 12 breaths (72 mcg) 4 times daily, as clinically tolerated. Subjects were assessed during Screening and Baseline to determine eligibility for the study. Once eligible, 5 Treatment Phase visits to the clinic were required at Week 4, Week 8, Week 12, Week 15, and Week 16 (final study visit). An Early Termination (ET) Visit was conducted for subjects who discontinued prior to Week 16; all assessments planned for the final Week 16 Visit were conducted during the ET Visit, if applicable. Subjects were contacted at least weekly by telephone or email to assess tolerance to study drug, adverse events (AEs), and changes to concomitant medications.”).</p> <p>[0082] (“Efficacy assessments consisted of 6MWD, plasma NT-proBNP concentration, and time to clinical worsening. Exploratory endpoints included SGRQ, change in DSP, time to exacerbation of underlying disease, and pulmonary function tests. Safety assessments consisted of the development of AEs, vital signs, clinical laboratory parameters, ECG parameters, hospitalizations due to cardiopulmonary</p>

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	<p>indications, exacerbations of underlying lung disease, and oxygenation.”).</p> <p>[0083] (“Treatment resulted in significantly fewer exacerbations of underlying lung disease over the 16-week treatment period (26.4% in Inhaled Treprostinil group and 38.7% in placebo group; p=0.018) and decreased risk of an exacerbation of underlying lung disease (hazard ratio 0.66 or 34% reduction in risk) as shown in FIG. 1.”).</p> <p>[0084] (“In addition, the following FVC suggestive data was obtained from this study. Among patients treated with inhaled treprostinil, overall results from intent to treat group were:</p> <p>Overall ITT</p> <p>28.47 mL and 44.40 mL in FVC at Weeks 8 and 16</p> <p>Percent predicted FVC at Week 8 (1.79%; p=0.0139) and Week 16 (1.80%; p=0.0277).</p> <p>Subset IIP etiology:</p> <p>46.48 mL and 108.18 mL (p=0.0229) at Weeks 8 and 16</p> <p>Percent predicted FVC at Week 8 (1.95%, p=0.0373) and Week 16 (2.88%; p=0.0096)</p> <p>Subset IPF etiology:</p> <p>84.52 mL and 168.52 mL (p=0.0108) at Weeks 8 and 16</p> <p>Percent predicted FVC at Week 8 (2.54%; p=0.0380) and Week 16 (3.50%; p=0.0147)</p> <p>Nintedanib: IPF - 109 mL (3.2% predicted) at 52 weeks</p> <p>Pirfenidone: IPF - 153-193 mL at 52 weeks</p> <p>Placebo corrected, rate of decline (not improvements)</p> <p>In comparison to the known treatments for ILD (nintedanib and pirfenidone) shown above, inhaled treprostinil achieves comparable effects with shorter treatment duration.”).</p>

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	<p>[0085] (“Pulmonary function testing was initially conducted as a safety assessment (Safety Population) during the study. The results indicated that although most PFT parameters remained stable for subjects in the study, a notable improvement in FVC (% predicted) was observed at Week 16 in the inhaled treprostinil group (median improvement of 1.0% compared to a 1.0% reduction in the placebo group). As a result, post hoc MMRM analyses ofFVC data were performed for the ITT Population and are presented in Table 1 (ITT Population), Table 2 (by PH ILD Etiology of IIP) and Table 3 (for subjects with IPF), shown below.”).</p> <p><b>Table 1</b> [<i>see</i> Claim 1, above.]</p> <p><b>Table 2</b> [<i>see</i> Claim 1, above.]</p> <p><b>Table 3</b> [<i>see</i> Claim 1, above.]</p> <p>[0086] (“Treatment with inhaled treprostinil resulted in improvements of 28.47 mL and 44.40 mL in FVC at Weeks 8 and 16, respectively; significant when presented as% predicted FVC at Week 8 (1.79%; p=0.0139) and Week 16 (1.80%; p=0.0277).”).</p> <p>[0087] (“When FVC was analyzed by PH-ILD etiology of IIP, treatment with inhaled treprostinil resulted in improvements of 46.48 mL and 108.18 mL (p=0.0229) when compared to placebo at Weeks 8 and 16, respectively. The between group differences for% predicted FVC were statistically significant at Week 8 (1.95%, p=0.0373) and Week 16 (2.88%; p=0.0096).”).</p> <p>[0088] (“Further analysis of FVC for subjects with an IPF etiology (using only the IIP subjects in the ITT Population), showed that treatment with inhaled treprostinil resulted in improvements of 84.52 mL and 168.52 mL (p=0.0108) compared to placebo at Weeks 8 and 16, respectively. The between group differences for% predicted FVC were statistically significant at Week 8 (2.54%; p=0.0380) and Week 16 (3.50%; p=0.0147).”).</p> <p>A POSA would read each and every one of these disclosures in light of the POSA’s understanding of the relevant art. UTC’s investigation into the facts relevant to this issue is ongoing and expert discovery is in its early stages. UTC thus offers the above support without waiver of its right to rely on the knowledge of a POSA to further establish priority to Provisional Application No. 63/011,810.</p>

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<p><b>3.</b> The method of claim 1, wherein said administering increases a 6 minutes walk distance of the patient by at least 10 m after 8 weeks, 12 weeks, or 16 weeks of the administering.</p>	<p>The disclosures cited <i>supra</i>, claim 1.</p> <p>[0080] (“An exacerbation of underlying lung disease is defined as an acute, clinically significant, respiratory deterioration characterized by evidence of new widespread alveolar abnormality (Collard et al., 2016). The present example shows that treatment with inhaled treprostinil resulted in significantly fewer exacerbations of underlying lung disease in patients.”).</p> <p>[0081] (“Subjects having underlying lung disease were treated with inhaled treprostinil over 16 weeks. Subjects initiated inhaled treprostinil or placebo at a dose of 3 breaths (18 mcg) 4 times daily (during waking hours). Study drug doses were maximized throughout the study. Dose escalations (additional 1 breath 4 times daily) could occur up to every 3 days with a target dosing regimen of 9 breaths (54 mcg) 4 times daily and a maximum dose of 12 breaths (72 mcg) 4 times daily, as clinically tolerated. Subjects were assessed during Screening and Baseline to determine eligibility for the study. Once eligible, 5 Treatment Phase visits to the clinic were required at Week 4, Week 8, Week 12, Week 15, and Week 16 (final study visit). An Early Termination (ET) Visit was conducted for subjects who discontinued prior to Week 16; all assessments planned for the final Week 16 Visit were conducted during the ET Visit, if applicable. Subjects were contacted at least weekly by telephone or email to assess tolerance to study drug, adverse events (AEs ), and changes to concomitant medications.”).</p> <p>[0082] (“Efficacy assessments consisted of 6MWD, plasma NT-proBNP concentration, and time to clinical worsening. Exploratory endpoints included SGRQ, change in DSP, time to exacerbation of underlying disease, and pulmonary function tests. Safety assessments consisted of the development of AEs, vital signs, clinical laboratory parameters, ECG parameters, hospitalizations due to cardiopulmonary indications, exacerbations of underlying lung disease, and oxygenation.”).</p> <p>[0083] (“Treatment resulted in significantly fewer exacerbations of underlying lung disease over the 16-week treatment period (26.4% in Inhaled Treprostinil group and 38.7% in placebo group; p=0.018) and decreased risk of an exacerbation of underlying lung disease (hazard ratio 0.66 or 34% reduction in risk) as shown in FIG. 1.”).</p>

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	<p>[0084] (“In addition, the following FVC suggestive data was obtained from this study. Among patients treated with inhaled treprostinil, overall results from intent to treat group were:</p> <p>Overall ITT</p> <p>28.47 mL and 44.40 mL in FVC at Weeks 8 and 16</p> <p>Percent predicted FVC at Week 8 (1.79%; p=0.0139) and Week 16 (1.80%; p=0.0277).</p> <p>Subset IIP etiology:</p> <p>46.48 mL and 108.18 mL (p=0.0229) at Weeks 8 and 16</p> <p>Percent predicted FVC at Week 8 (1.95%, p=0.0373) and Week 16 (2.88%; p=0.0096)</p> <p>Subset IPF etiology:</p> <p>84.52 mL and 168.52 mL (p=0.0108) at Weeks 8 and 16</p> <p>Percent predicted FVC at Week 8 (2.54%; p=0.0380) and Week 16 (3.50%; p=0.0147)</p> <p>Nintedanib: IPF - 109 mL (3.2% predicted) at 52 weeks</p> <p>Pirfenidone: IPF - 153-193 mL at 52 weeks</p> <p>Placebo corrected, rate of decline (not improvements)</p> <p>In comparison to the known treatments for ILD (nintedanib and pirfenidone) shown above, inhaled treprostinil achieves comparable effects with shorter treatment duration.”).</p> <p>[0085] (“Pulmonary function testing was initially conducted as a safety assessment (Safety Population) during the study. The results indicated that although most PFT parameters remained stable for subjects in the study, a notable improvement in FVC (% predicted) was observed at Week 16 in the inhaled treprostinil group (median improvement of 1.0% compared to a 1.0% reduction in the placebo group). As a result, post hoc MMRM analyses of FVC data were performed for the ITT Population and are presented in Table 1 (ITT</p>

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	<p>Population), Table 2 (by PH ILD Etiology of IIP) and Table 3 (for subjects with IPF), shown below.”).</p> <p><b>Table 1</b> [<i>see</i> Claim 1, above.]</p> <p><b>Table 2</b> [<i>see</i> Claim 1, above.]</p> <p><b>Table 3</b> [<i>see</i> Claim 1, above.]</p> <p>[0086] (“Treatment with inhaled treprostinil resulted in improvements of 28.47 mL and 44.40 mL in FVC at Weeks 8 and 16, respectively; significant when presented as% predicted FVC at Week 8 (1.79%; p=0.0139) and Week 16 (1.80%; p=0.0277).”).</p> <p>[0087] (“When FVC was analyzed by PH-ILD etiology of IIP, treatment with inhaled treprostinil resulted in improvements of 46.48 mL and 108.18 mL (p=0.0229) when compared to placebo at Weeks 8 and 16, respectively. The between group differences for% predicted FVC were statistically significant at Week 8 (1.95%, p=0.0373) and Week 16 (2.88%; p=0.0096).”).</p> <p>[0088] (“Further analysis of FVC for subjects with an IPF etiology (using only the IIP subjects in the ITT Population), showed that treatment with inhaled treprostinil resulted in improvements of 84.52 mL and 168.52 mL (p=0.0108) compared to placebo at Weeks 8 and 16, respectively. The between group differences for% predicted FVC were statistically significant at Week 8 (2.54%; p=0.0380) and Week 16 (3.50%; p=0.0147).”).</p> <p>A POSA would read each and every one of these disclosures in light of the POSA’s understanding of the relevant art. UTC’s investigation into the facts relevant to this issue is ongoing and expert discovery is in its early stages. UTC thus offers the above support without waiver of its right to rely on the knowledge of a POSA to further establish priority to Provisional Application No. 63/011,810.</p>
4. The method of claim 1, wherein said administering provides a statistically significant reduction of a plasma concentration of NT-proBNP in the patient	<p>The disclosures cited <i>supra</i>, claim 1.</p> <p>[0080] (“An exacerbation of underlying lung disease is defined as an acute, clinically significant, respiratory deterioration characterized by evidence of new widespread alveolar abnormality (Collard et al., 2016). The present example shows that treatment with inhaled treprostinil resulted in significantly fewer exacerbations of underlying lung disease in patients.”).</p>

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after 8 weeks, 12 weeks, or 16 weeks of the administering.	<p>[0081] (“Subjects having underlying lung disease were treated with inhaled treprostinil over 16 weeks. Subjects initiated inhaled treprostinil or placebo at a dose of 3 breaths (18 mcg) 4 times daily (during waking hours). Study drug doses were maximized throughout the study. Dose escalations (additional 1 breath 4 times daily) could occur up to every 3 days with a target dosing regimen of 9 breaths (54 mcg) 4 times daily and a maximum dose of 12 breaths (72 mcg) 4 times daily, as clinically tolerated. Subjects were assessed during Screening and Baseline to determine eligibility for the study. Once eligible, 5 Treatment Phase visits to the clinic were required at Week 4, Week 8, Week 12, Week 15, and Week 16 (final study visit). An Early Termination (ET) Visit was conducted for subjects who discontinued prior to Week 16; all assessments planned for the final Week 16 Visit were conducted during the ET Visit, if applicable. Subjects were contacted at least weekly by telephone or email to assess tolerance to study drug, adverse events (AEs), and changes to concomitant medications.”).</p> <p>[0082] (“Efficacy assessments consisted of 6MWD, plasma NT-proBNP concentration, and time to clinical worsening. Exploratory endpoints included SGRQ, change in DSP, time to exacerbation of underlying disease, and pulmonary function tests. Safety assessments consisted of the development of AEs, vital signs, clinical laboratory parameters, ECG parameters, hospitalizations due to cardiopulmonary indications, exacerbations of underlying lung disease, and oxygenation.”).</p> <p>[0083] (“Treatment resulted in significantly fewer exacerbations of underlying lung disease over the 16-week treatment period (26.4% in Inhaled Treprostinil group and 38.7% in placebo group; p=0.018) and decreased risk of an exacerbation of underlying lung disease (hazard ratio 0.66 or 34% reduction in risk) as shown in FIG. 1.”).</p> <p>[0084] (“In addition, the following FVC suggestive data was obtained from this study. Among patients treated with inhaled treprostinil, overall results from intent to treat group were:</p> <p>Overall ITT</p> <p>28.47 mL and 44.40 mL in FVC at Weeks 8 and 16</p> <p>Percent predicted FVC at Week 8 (1.79%; p=0.0139) and Week 16 (1.80%; p=0.0277).</p>

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	<p>Subset IIP etiology:</p> <p>46.48 mL and 108.18 mL (p=0.0229) at Weeks 8 and 16</p> <p>Percent predicted FVC at Week 8 (1.95%, p=0.0373) and Week 16 (2.88%; p=0.0096)</p> <p>Subset IPF etiology:</p> <p>84.52 mL and 168.52 mL (p=0.0108) at Weeks 8 and 16</p> <p>Percent predicted FVC at Week 8 (2.54%; p=0.0380) and Week 16 (3.50%; p=0.0147)</p> <p>Nintedanib: IPF - 109 mL (3.2% predicted) at 52 weeks</p> <p>Pirfenidone: IPF - 153-193 mL at 52 weeks</p> <p>Placebo corrected, rate of decline (not improvements)</p> <p>In comparison to the known treatments for ILD (nintedanib and pirfenidone) shown above, inhaled treprostinil achieves comparable effects with shorter treatment duration.”).</p> <p>[0085] (“Pulmonary function testing was initially conducted as a safety assessment (Safety Population) during the study. The results indicated that although most PFT parameters remained stable for subjects in the study, a notable improvement in FVC (% predicted) was observed at Week 16 in the inhaled treprostinil group (median improvement of 1.0% compared to a 1.0% reduction in the placebo group). As a result, post hoc MMRM analyses of FVC data were performed for the ITT Population and are presented in Table 1 (ITT Population), Table 2 (by PH ILD Etiology of IIP) and Table 3 (for subjects with IPF), shown below.”).</p> <p><b>Table 1</b> [see Claim 1, above.]</p> <p><b>Table 2</b> [see Claim 1, above.]</p> <p><b>Table 3</b> [see Claim 1, above.]</p> <p>[0086] (“Treatment with inhaled treprostinil resulted in improvements of 28.47 mL and 44.40 mL in FVC at Weeks 8 and 16, respectively;</p>

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	<p>significant when presented as% predicted FVC at Week 8 (1.79%; p=0.0139) and Week 16 (1.80%; p=0.0277).”).</p> <p>[0087] (“When FVC was analyzed by PH-ILD etiology of IIP, treatment with inhaled treprostinil resulted in improvements of 46.48 mL and 108.18 mL (p=0.0229) when compared to placebo at Weeks 8 and 16, respectively. The between group differences for% predicted FVC were statistically significant at Week 8 (1.95%, p=0.0373) and Week 16 (2.88%; p=0.0096).”).</p> <p>[0088] (“Further analysis of FVC for subjects with an IPF etiology (using only the IIP subjects in the ITT Population), showed that treatment with inhaled treprostinil resulted in improvements of 84.52 mL and 168.52 mL (p=0.0108) compared to placebo at Weeks 8 and 16, respectively. The between group differences for% predicted FVC were statistically significant at Week 8 (2.54%; p=0.0380) and Week 16 (3.50%; p=0.0147).”).</p> <p>A POSA would read each and every one of these disclosures in light of the POSA’s understanding of the relevant art. UTC’s investigation into the facts relevant to this issue is ongoing and expert discovery is in its early stages. UTC thus offers the above support without waiver of its right to rely on the knowledge of a POSA to further establish priority to Provisional Application No. 63/011,810.</p>
<p><b>5.</b> The method of claim 1, wherein said administering reduces a plasma concentration of NT-proBNP in the patient by at least 200 pg/ml after 8 weeks, 12 weeks, or 16 weeks of the administering.</p>	<p>The disclosures cited <i>supra</i>, claim 1.</p> <p>[0080] (“An exacerbation of underlying lung disease is defined as an acute, clinically significant, respiratory deterioration characterized by evidence of new widespread alveolar abnormality (Collard et al., 2016). The present example shows that treatment with inhaled treprostinil resulted in significantly fewer exacerbations of underlying lung disease in patients.”).</p> <p>[0081] (“Subjects having underlying lung disease were treated with inhaled treprostinil over 16 weeks. Subjects initiated inhaled treprostinil or placebo at a dose of 3 breaths (18 mcg) 4 times daily (during waking hours). Study drug doses were maximized throughout the study. Dose escalations (additional 1 breath 4 times daily) could occur up to every 3 days with a target dosing regimen of 9 breaths (54 mcg) 4 times daily and a maximum dose of 12 breaths (72 mcg) 4 times daily, as clinically tolerated. Subjects were assessed during Screening and Baseline to determine eligibility for the study. Once eligible, 5 Treatment Phase visits to the clinic were required at Week 4, Week 8, Week 12, Week 15, and Week 16 (final study visit). An</p>

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	<p>Early Termination (ET) Visit was conducted for subjects who discontinued prior to Week 16; all assessments planned for the final Week 16 Visit were conducted during the ET Visit, if applicable. Subjects were contacted at least weekly by telephone or email to assess tolerance to study drug, adverse events (AEs), and changes to concomitant medications.”).</p> <p>[0082] (“Efficacy assessments consisted of 6MWD, plasma NT-proBNP concentration, and time to clinical worsening. Exploratory endpoints included SGRQ, change in DSP, time to exacerbation of underlying disease, and pulmonary function tests. Safety assessments consisted of the development of AEs, vital signs, clinical laboratory parameters, ECG parameters, hospitalizations due to cardiopulmonary indications, exacerbations of underlying lung disease, and oxygenation.”).</p> <p>[0083] (“Treatment resulted in significantly fewer exacerbations of underlying lung disease over the 16-week treatment period (26.4% in Inhaled Treprostinil group and 38.7% in placebo group; p=0.018) and decreased risk of an exacerbation of underlying lung disease (hazard ratio 0.66 or 34% reduction in risk) as shown in FIG. 1.”).</p> <p>[0084] (“In addition, the following FVC suggestive data was obtained from this study. Among patients treated with inhaled treprostinil, overall results from intent to treat group were:</p> <p>Overall ITT</p> <p>28.47 mL and 44.40 mL in FVC at Weeks 8 and 16</p> <p>Percent predicted FVC at Week 8 (1.79%; p=0.0139) and Week 16 (1.80%; p=0.0277).</p> <p>Subset IIP etiology:</p> <p>46.48 mL and 108.18 mL (p=0.0229) at Weeks 8 and 16</p> <p>Percent predicted FVC at Week 8 (1.95%, p=0.0373) and Week 16 (2.88%; p=0.0096)</p> <p>Subset IPF etiology:</p> <p>84.52 mL and 168.52 mL (p=0.0108) at Weeks 8 and 16</p>

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	<p>Percent predicted FVC at Week 8 (2.54%; p=0.0380) and Week 16 (3.50%; p=0.0147)</p> <p>Nintedanib: IPF - 109 mL (3.2% predicted) at 52 weeks</p> <p>Pirfenidone: IPF - 153-193 mL at 52 weeks</p> <p>Placebo corrected, rate of decline (not improvements)</p> <p>In comparison to the known treatments for ILD (nintedanib and pirfenidone) shown above, inhaled treprostinil achieves comparable effects with shorter treatment duration.”).</p> <p>[0085] (“Pulmonary function testing was initially conducted as a safety assessment (Safety Population) during the study. The results indicated that although most PFT parameters remained stable for subjects in the study, a notable improvement in FVC (% predicted) was observed at Week 16 in the inhaled treprostinil group (median improvement of 1.0% compared to a 1.0% reduction in the placebo group). As a result, post hoc MMRM analyses of FVC data were performed for the ITT Population and are presented in Table 1 (ITT Population), Table 2 (by PH ILD Etiology of IIP) and Table 3 (for subjects with IPF), shown below.”).</p> <p><b>Table 1</b> [see Claim 1, above.]</p> <p><b>Table 2</b> [see Claim 1, above.]</p> <p><b>Table 3</b> [see Claim 1, above.]</p> <p>[0086] (“Treatment with inhaled treprostinil resulted in improvements of 28.47 mL and 44.40 mL in FVC at Weeks 8 and 16, respectively; significant when presented as % predicted FVC at Week 8 (1.79%; p=0.0139) and Week 16 (1.80%; p=0.0277).”).</p> <p>[0087] (“When FVC was analyzed by PH-ILD etiology of IIP, treatment with inhaled treprostinil resulted in improvements of 46.48 mL and 108.18 mL (p=0.0229) when compared to placebo at Weeks 8 and 16, respectively. The between group differences for % predicted FVC were statistically significant at Week 8 (1.95%, p=0.0373) and Week 16 (2.88%; p=0.0096).”).</p> <p>[0088] (“Further analysis of FVC for subjects with an IPF etiology (using only the IIP subjects in the ITT Population), showed that</p>

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	<p>treatment with inhaled treprostinil resulted in improvements of 84.52 mL and 168.52 mL (<math>p=0.0108</math>) compared to placebo at Weeks 8 and 16, respectively. The between group differences for% predicted FVC were statistically significant at Week 8 (2.54%; <math>p=0.0380</math>) and Week 16 (3.50%; <math>p=0.0147</math>).”).</p> <p>A POSA would read each and every one of these disclosures in light of the POSA’s understanding of the relevant art. UTC’s investigation into the facts relevant to this issue is ongoing and expert discovery is in its early stages. UTC thus offers the above support without waiver of its right to rely on the knowledge of a POSA to further establish priority to Provisional Application No. 63/011,810.</p>
<p><b>6.</b> The method of claim 1, wherein said administering provides a statistically significant reduction of at least one exacerbations of the interstitial lung disease.</p>	<p>The disclosures cited <i>supra</i>, claim 1.</p> <p>[0080] (“The present example shows that treatment with inhaled treprostinil resulted in significantly fewer exacerbations of underlying lung disease in patients.”).</p> <p>[0083] (“Treatment resulted in significantly fewer exacerbations of underlying lung disease over the 16-week treatment period (26.4% in Inhaled Treprostinil group and 38.7% in placebo group; <math>p=0.018</math>) and decreased risk of an exacerbation of underlying lung disease (hazard ratio 0.66 or 34% reduction in risk) as shown in FIG. 1.”).</p> <p>A POSA would read each and every one of these disclosures in light of the POSA’s understanding of the relevant art. UTC’s investigation into the facts relevant to this issue is ongoing and expert discovery is in its early stages. UTC thus offers the above support without waiver of its right to rely on the knowledge of a POSA to further establish priority to Provisional Application No. 63/011,810.</p>
<p><b>7.</b> The method of claim 1, wherein said administering provides a statistically significant reduction of clinical worsening events due to the interstitial lung disease.</p>	<p>The disclosures cited <i>supra</i>, claim 1.</p> <p><b>Figure 1</b></p> <p>[0080] (“An exacerbation of underlying lung disease is defined as an acute, clinically significant, respiratory deterioration characterized by evidence of new widespread alveolar abnormality (Collard et al., 2016). The present example shows that treatment with inhaled treprostinil resulted in significantly fewer exacerbations of underlying lung disease in patients.”).</p> <p>[0081] (“Subjects having underlying lung disease were treated with inhaled treprostinil over 16 weeks. Subjects initiated inhaled treprostinil or placebo at a dose of 3 breaths (18 mcg) 4 times daily</p>

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	<p>(during waking hours). Study drug doses were maximized throughout the study. Dose escalations (additional 1 breath 4 times daily) could occur up to every 3 days with a target dosing regimen of 9 breaths (54 mcg) 4 times daily and a maximum dose of 12 breaths (72 mcg) 4 times daily, as clinically tolerated. Subjects were assessed during Screening and Baseline to determine eligibility for the study. Once eligible, 5 Treatment Phase visits to the clinic were required at Week 4, Week 8, Week 12, Week 15, and Week 16 (final study visit). An Early Termination (ET) Visit was conducted for subjects who discontinued prior to Week 16; all assessments planned for the final Week 16 Visit were conducted during the ET Visit, if applicable. Subjects were contacted at least weekly by telephone or email to assess tolerance to study drug, adverse events (AEs), and changes to concomitant medications.”).</p> <p>[0082] (“Efficacy assessments consisted of 6MWD, plasma NT-proBNP concentration, and time to clinical worsening. Exploratory endpoints included SGRQ, change in DSP, time to exacerbation of underlying disease, and pulmonary function tests. Safety assessments consisted of the development of AEs, vital signs, clinical laboratory parameters, ECG parameters, hospitalizations due to cardiopulmonary indications, exacerbations of underlying lung disease, and oxygenation.”).</p> <p>[0083] (“Treatment resulted in significantly fewer exacerbations of underlying lung disease over the 16-week treatment period (26.4% in Inhaled Treprostinil group and 38.7% in placebo group; p=0.018) and decreased risk of an exacerbation of underlying lung disease (hazard ratio 0.66 or 34% reduction in risk) as shown in FIG. 1.”).</p> <p>A POSA would read each and every one of these disclosures in light of the POSA’s understanding of the relevant art. UTC’s investigation into the facts relevant to this issue is ongoing and expert discovery is in its early stages. UTC thus offers the above support without waiver of its right to rely on the knowledge of a POSA to further establish priority to Provisional Application No. 63/011,810.</p>
8. The method of claim 7, wherein the clinical worsening events comprise at least one hospitalization for cardiopulmonary indication and a	<p>The disclosures cited <i>supra</i>, claim 1, 7.</p> <p><b>Figure 1</b></p> <p>[0080] (“An exacerbation of underlying lung disease is defined as an acute, clinically significant, respiratory deterioration characterized by evidence of new widespread alveolar abnormality (Collard et al., 2016). The present example shows that treatment with inhaled</p>

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<p>decrease in a 6-minute walk distance by more than 15% compared a baseline 6-minute walk distance prior to the administering.</p>	<p>treprostinil resulted in significantly fewer exacerbations of underlying lung disease in patients.”).</p> <p>[0081] (“Subjects having underlying lung disease were treated with inhaled treprostinil over 16 weeks. Subjects initiated inhaled treprostinil or placebo at a dose of 3 breaths (18 mcg) 4 times daily (during waking hours). Study drug doses were maximized throughout the study. Dose escalations (additional 1 breath 4 times daily) could occur up to every 3 days with a target dosing regimen of 9 breaths (54 mcg) 4 times daily and a maximum dose of 12 breaths (72 mcg) 4 times daily, as clinically tolerated. Subjects were assessed during Screening and Baseline to determine eligibility for the study. Once eligible, 5 Treatment Phase visits to the clinic were required at Week 4, Week 8, Week 12, Week 15, and Week 16 (final study visit). An Early Termination (ET) Visit was conducted for subjects who discontinued prior to Week 16; all assessments planned for the final Week 16 Visit were conducted during the ET Visit, if applicable. Subjects were contacted at least weekly by telephone or email to assess tolerance to study drug, adverse events (AEs), and changes to concomitant medications.”).</p> <p>[0082] (“Efficacy assessments consisted of 6MWD, plasma NT-proBNP concentration, and time to clinical worsening. Exploratory endpoints included SGRQ, change in DSP, time to exacerbation of underlying disease, and pulmonary function tests. Safety assessments consisted of the development of AEs, vital signs, clinical laboratory parameters, ECG parameters, hospitalizations due to cardiopulmonary indications, exacerbations of underlying lung disease, and oxygenation.”).</p> <p>[0083] (“Treatment resulted in significantly fewer exacerbations of underlying lung disease over the 16-week treatment period (26.4% in Inhaled Treprostinil group and 38.7% in placebo group; p=0.018) and decreased risk of an exacerbation of underlying lung disease (hazard ratio 0.66 or 34% reduction in risk) as shown in FIG. 1.”).</p> <p>A POSA would read each and every one of these disclosures in light of the POSA’s understanding of the relevant art. UTC’s investigation into the facts relevant to this issue is ongoing and expert discovery is in its early stages. UTC thus offers the above support without waiver of its right to rely on the knowledge of a POSA to further establish priority to Provisional Application No. 63/011,810.</p>
<p><b>9.</b> The method of claim 1, wherein said</p>	<p>The disclosures cited <i>supra</i>, claim 1.</p>

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<p>administering provides a statistically significant improves of forced vital capacity (FVC) in the patient after 8 weeks, 12 weeks or 16 weeks of the administering.</p>	<p>[0080] (“An exacerbation of underlying lung disease is defined as an acute, clinically significant, respiratory deterioration characterized by evidence of new widespread alveolar abnormality (Collard et al., 2016). The present example shows that treatment with inhaled treprostinil resulted in significantly fewer exacerbations of underlying lung disease in patients.”).</p> <p>[0081] (“Subjects having underlying lung disease were treated with inhaled treprostinil over 16 weeks. Subjects initiated inhaled treprostinil or placebo at a dose of 3 breaths (18 mcg) 4 times daily (during waking hours). Study drug doses were maximized throughout the study. Dose escalations (additional 1 breath 4 times daily) could occur up to every 3 days with a target dosing regimen of 9 breaths (54 mcg) 4 times daily and a maximum dose of 12 breaths (72 mcg) 4 times daily, as clinically tolerated. Subjects were assessed during Screening and Baseline to determine eligibility for the study. Once eligible, 5 Treatment Phase visits to the clinic were required at Week 4, Week 8, Week 12, Week 15, and Week 16 (final study visit). An Early Termination (ET) Visit was conducted for subjects who discontinued prior to Week 16; all assessments planned for the final Week 16 Visit were conducted during the ET Visit, if applicable. Subjects were contacted at least weekly by telephone or email to assess tolerance to study drug, adverse events (AEs ), and changes to concomitant medications.”).</p> <p>[0082] (“Efficacy assessments consisted of 6MWD, plasma NT-proBNP concentration, and time to clinical worsening. Exploratory endpoints included SGRQ, change in DSP, time to exacerbation of underlying disease, and pulmonary function tests. Safety assessments consisted of the development of AEs, vital signs, clinical laboratory parameters, ECG parameters, hospitalizations due to cardiopulmonary indications, exacerbations of underlying lung disease, and oxygenation.”).</p> <p>[0083] (“Treatment resulted in significantly fewer exacerbations of underlying lung disease over the 16-week treatment period (26.4% in Inhaled Treprostinil group and 38.7% in placebo group; p=0.018) and decreased risk of an exacerbation of underlying lung disease (hazard ratio 0.66 or 34% reduction in risk) as shown in FIG. 1.”)</p> <p>[0084] (“In addition, the following FVC suggestive data was obtained from this study. Among patients treated with inhaled treprostinil, overall results from intent to treat group were:</p>

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	<p>Overall ITT</p> <p>28.47 mL and 44.40 mL in FVC at Weeks 8 and 16</p> <p>Percent predicted FVC at Week 8 (1.79%; p=0.0139) and Week 16 (1.80%; p=0.0277).</p> <p>Subset IIP etiology:</p> <p>46.48 mL and 108.18 mL (p=0.0229) at Weeks 8 and 16</p> <p>Percent predicted FVC at Week 8 (1.95%, p=0.0373) and Week 16 (2.88%; p=0.0096)</p> <p>Subset IPF etiology:</p> <p>84.52 mL and 168.52 mL (p=0.0108) at Weeks 8 and 16</p> <p>Percent predicted FVC at Week 8 (2.54%; p=0.0380) and Week 16 (3.50%; p=0.0147)</p> <p>Nintedanib: IPF - 109 mL (3.2% predicted) at 52 weeks</p> <p>Pirfenidone: IPF - 153-193 mL at 52 weeks</p> <p>Placebo corrected, rate of decline (not improvements)</p> <p>In comparison to the known treatments for ILD (nintedanib and pirfenidone) shown above, inhaled treprostinil achieves comparable effects with shorter treatment duration.”).</p> <p>[0085] (“Pulmonary function testing was initially conducted as a safety assessment (Safety Population) during the study. The results indicated that although most PFT parameters remained stable for subjects in the study, a notable improvement in FVC (% predicted) was observed at Week 16 in the inhaled treprostinil group (median improvement of 1.0% compared to a 1.0% reduction in the placebo group). As a result, post hoc MMRM analyses of FVC data were performed for the ITT Population and are presented in Table 1 (ITT Population), Table 2 (by PH ILD Etiology of IIP) and Table 3 (for subjects with IPF), shown below.”).</p> <p><b>Table 1</b> [see Claim 1, above.]</p>

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	<p><b>Table 2</b> [see Claim 1, above.]</p> <p><b>Table 3</b> [see Claim 1, above.]</p> <p>[0086] (“Treatment with inhaled treprostinil resulted in improvements of 28.47 mL and 44.40 mL in FVC at Weeks 8 and 16, respectively; significant when presented as% predicted FVC at Week 8 (1.79%; p=0.0139) and Week 16 (1.80%; p=0.0277).”).</p> <p>[0087] (“When FVC was analyzed by PH-ILD etiology of IIP, treatment with inhaled treprostinil resulted in improvements of 46.48 mL and 108.18 mL (p=0.0229) when compared to placebo at Weeks 8 and 16, respectively. The between group differences for% predicted FVC were statistically significant at Week 8 (1.95%, p=0.0373) and Week 16 (2.88%; p=0.0096).”).</p> <p>[0088] (“Further analysis of FVC for subjects with an IPF etiology (using only the IIP subjects in the ITT Population), showed that treatment with inhaled treprostinil resulted in improvements of 84.52 mL and 168.52 mL (p=0.0108) compared to placebo at Weeks 8 and 16, respectively. The between group differences for% predicted FVC were statistically significant at Week 8 (2.54%; p=0.0380) and Week 16 (3.50%; p=0.0147).”).</p> <p>A POSA would read each and every one of these disclosures in light of the POSA’s understanding of the relevant art. UTC’s investigation into the facts relevant to this issue is ongoing and expert discovery is in its early stages. UTC thus offers the above support without waiver of its right to rely on the knowledge of a POSA to further establish priority to Provisional Application No. 63/011,810.</p>
<p><b>10.</b> The method of claim 9, wherein said administering improves the forced vital capacity (FVC) in the patient by at least 20 ml after 8 weeks, 12 weeks, or 16 weeks of the administering.</p>	<p>The disclosures cited <i>supra</i>, claims 1, 9.</p> <p>[0080] (“An exacerbation of underlying lung disease is defined as an acute, clinically significant, respiratory deterioration characterized by evidence of new widespread alveolar abnormality (Collard et al., 2016). The present example shows that treatment with inhaled treprostinil resulted in significantly fewer exacerbations of underlying lung disease in patients.”).</p> <p>[0081] (“Subjects having underlying lung disease were treated with inhaled treprostinil over 16 weeks. Subjects initiated inhaled treprostinil or placebo at a dose of 3 breaths (18 mcg) 4 times daily (during waking hours). Study drug doses were maximized throughout the study. Dose escalations (additional 1 breath 4 times daily) could</p>

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	<p>occur up to every 3 days with a target dosing regimen of 9 breaths (54 mcg) 4 times daily and a maximum dose of 12 breaths (72 mcg) 4 times daily, as clinically tolerated. Subjects were assessed during Screening and Baseline to determine eligibility for the study. Once eligible, 5 Treatment Phase visits to the clinic were required at Week 4, Week 8, Week 12, Week 15, and Week 16 (final study visit). An Early Termination (ET) Visit was conducted for subjects who discontinued prior to Week 16; all assessments planned for the final Week 16 Visit were conducted during the ET Visit, if applicable. Subjects were contacted at least weekly by telephone or email to assess tolerance to study drug, adverse events (AEs), and changes to concomitant medications.”).</p> <p>[0082] (“Efficacy assessments consisted of 6MWD, plasma NT-proBNP concentration, and time to clinical worsening. Exploratory endpoints included SGRQ, change in DSP, time to exacerbation of underlying disease, and pulmonary function tests. Safety assessments consisted of the development of AEs, vital signs, clinical laboratory parameters, ECG parameters, hospitalizations due to cardiopulmonary indications, exacerbations of underlying lung disease, and oxygenation.”).</p> <p>[0083] (“Treatment resulted in significantly fewer exacerbations of underlying lung disease over the 16-week treatment period (26.4% in Inhaled Treprostinil group and 38.7% in placebo group; p=0.018) and decreased risk of an exacerbation of underlying lung disease (hazard ratio 0.66 or 34% reduction in risk) as shown in FIG. 1.”).</p> <p>[0084] (“In addition, the following FVC suggestive data was obtained from this study. Among patients treated with inhaled treprostinil, overall results from intent to treat group were:</p> <p>Overall ITT</p> <p>28.47 mL and 44.40 mL in FVC at Weeks 8 and 16</p> <p>Percent predicted FVC at Week 8 (1.79%; p=0.0139) and Week 16 (1.80%; p=0.0277).</p> <p>Subset IIP etiology:</p> <p>46.48 mL and 108.18 mL (p=0.0229) at Weeks 8 and 16</p>

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	<p>Percent predicted FVC at Week 8 (1.95%, p=0.0373) and Week 16 (2.88%; p=0.0096)</p> <p>Subset IPF etiology:</p> <p>84.52 mL and 168.52 mL (p=0.0108) at Weeks 8 and 16</p> <p>Percent predicted FVC at Week 8 (2.54%; p=0.0380) and Week 16 (3.50%; p=0.0147)</p> <p>Nintedanib: IPF - 109 mL (3.2% predicted) at 52 weeks</p> <p>Pirfenidone: IPF - 153-193 mL at 52 weeks</p> <p>Placebo corrected, rate of decline (not improvements)</p> <p>In comparison to the known treatments for ILD (nintedanib and pirfenidone) shown above, inhaled treprostinil achieves comparable effects with shorter treatment duration.”).</p> <p>[0085] (“Pulmonary function testing was initially conducted as a safety assessment (Safety Population) during the study. The results indicated that although most PFT parameters remained stable for subjects in the study, a notable improvement in FVC (% predicted) was observed at Week 16 in the inhaled treprostinil group (median improvement of 1.0% compared to a 1.0% reduction in the placebo group). As a result, post hoc MMRM analyses of FVC data were performed for the ITT Population and are presented in Table 1 (ITT Population), Table 2 (by PH ILD Etiology of IIP) and Table 3 (for subjects with IPF), shown below.”).</p> <p><b>Table 1</b> [see Claim 1, above.]</p> <p><b>Table 2</b> [see Claim 1, above.]</p> <p><b>Table 3</b> [see Claim 1, above.]</p> <p>[0086] (“Treatment with inhaled treprostinil resulted in improvements of 28.47 mL and 44.40 mL in FVC at Weeks 8 and 16, respectively; significant when presented as % predicted FVC at Week 8 (1.79%; p=0.0139) and Week 16 (1.80%; p=0.0277).”).</p> <p>[0087] (“When FVC was analyzed by PH-ILD etiology of IIP, treatment with inhaled treprostinil resulted in improvements of 46.48</p>

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	<p>mL and 108.18 mL (p=0.0229) when compared to placebo at Weeks 8 and 16, respectively. The between group differences for% predicted FVC were statistically significant at Week 8 (1.95%, p=0.0373) and Week 16 (2.88%; p=0.0096).”).</p> <p>[0088] (“Further analysis of FVC for subjects with an IPF etiology (using only the IIP subjects in the ITT Population), showed that treatment with inhaled treprostinil resulted in improvements of 84.52 mL and 168.52 mL (p=0.0108) compared to placebo at Weeks 8 and 16, respectively. The between group differences for% predicted FVC were statistically significant at Week 8 (2.54%; p=0.0380) and Week 16 (3.50%; p=0.0147).”).</p> <p>A POSA would read each and every one of these disclosures in light of the POSA’s understanding of the relevant art. UTC’s investigation into the facts relevant to this issue is ongoing and expert discovery is in its early stages. UTC thus offers the above support without waiver of its right to rely on the knowledge of a POSA to further establish priority to Provisional Application No. 63/011,810.</p>
<b>11.</b> The method of claim 1, wherein said administering is performed by a pulsed inhalation device.	<p>The disclosures cited <i>supra</i>, claim 1.</p> <p>[0048] (“Further aspects of the present invention are concerned with the use of treprostinil or its derivatives, prodrugs, esters, or pharmaceutically acceptable salts thereof, in the manufacture of a medicament for the treatment or prevention of interstitial lung disease or a condition associated with interstitial lung disease. In some embodiments, the medicament is formulated for inhalation. When administered by inhalation, the formulation can be nebulized or formulated for a dry powder inhaler (DPI).”).</p> <p>[0060] (“In preferred embodiments, treprostinil is administered via inhalation. Inhaled compositions comprising treprostinil may include sprays, aerosols, and dry powder compositions. Said compositions may include a variety of excipients. Inhalable compositions administered may include any of those described in U.S. Patent No. 9,339,507 (including the commercial product Tyvaso® (treprostinil) Inhalation Solution), PCT/US2017/031301 and PCT/US2013/072647, the entire disclosures of which are hereby incorporated by reference.”).<sup>9</sup></p>

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<sup>9</sup> A POSA would consider the contents of U.S. Patent No. 9,339,507, PCT/US2017/031301, and PCT/US2013/072647 in their entirety.

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	<p>[0081] (“Subjects having underlying lung disease were treated with inhaled treprostinil over 16 weeks. Subjects initiated inhaled treprostinil or placebo at a dose of 3 breaths (18 mcg) 4 times daily (during waking hours). Study drug doses were maximized throughout the study. Dose escalations (additional 1 breath 4 times daily) could occur up to every 3 days with a target dosing regimen of 9 breaths (54 mcg) 4 times daily and a maximum dose of 12 breaths (72 mcg) 4 times daily, as clinically tolerated. Subjects were assessed during Screening and Baseline to determine eligibility for the study. Once eligible, 5 Treatment Phase visits to the clinic were required at Week 4, Week 8, Week 12, Week 15, and Week 16 (final study visit). An Early Termination (ET) Visit was conducted for subjects who discontinued prior to Week 16; all assessments planned for the final Week 16 Visit were conducted during the ET Visit, if applicable. Subjects were contacted at least weekly by telephone or email to assess tolerance to study drug, adverse events (AEs ), and changes to concomitant medications.”).</p> <p>A POSA would read each and every one of these disclosures in light of the POSA’s understanding of the relevant art. UTC’s investigation into the facts relevant to this issue is ongoing and expert discovery is in its early stages. UTC thus offers the above support without waiver of its right to rely on the knowledge of a POSA to further establish priority to Provisional Application No. 63/011,810.</p>
14. The method of claim 11, wherein the pulsed inhalation device is a dry powder inhaler	<p>The disclosures cited <i>supra</i>, claims 1, 11.</p> <p>A POSA would read each and every one of these disclosures in light of the POSA’s understanding of the relevant art. UTC’s investigation into the facts relevant to this issue is ongoing and expert discovery is in its early stages. UTC thus offers the above support without waiver of its right to rely on the knowledge of a POSA to further establish priority to Provisional Application No. 63/011,810.</p>
comprising a dry powder comprising treprostinil or a pharmaceutically acceptable salt thereof.	<p>The disclosures cited <i>supra</i>, claims 1, 11, 14.</p> <p>[0075] (“The term ‘dry powder’ in reference to the composition of the invention, refers to a powder, granulate, tablet form composition, or any other solid form with a humidity content that assures to the composition chemical stability in time. More precisely, the term ‘dry’ refers to a solid composition with water content lower than 10% w/w, normally less than 5% and preferably less than 3%.”).</p> <p>A POSA would read each and every one of these disclosures in light of the POSA’s understanding of the relevant art. UTC’s investigation into the facts relevant to this issue is ongoing and expert discovery is</p>

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	in its early stages. UTC thus offers the above support without waiver of its right to rely on the knowledge of a POSA to further establish priority to Provisional Application No. 63/011,810.
<b>15.</b> The method of claim 1, wherein the effective amount of treprostinil or a pharmaceutically acceptable salt administered to the patient in a single inhalation administration event is from 15 µg to 100 µg.	<p>The disclosures cited <i>supra</i>, claim 1.</p> <p>[0081] (“Subjects having underlying lung disease were treated with inhaled treprostinil over 16 weeks. Subjects initiated inhaled treprostinil or placebo at a dose of 3 breaths (18 mcg) 4 times daily (during waking hours). Study drug doses were maximized throughout the study. Dose escalations (additional 1 breath 4 times daily) could occur up to every 3 days with a target dosing regimen of 9 breaths (54 mcg) 4 times daily and a maximum dose of 12 breaths (72 mcg) 4 times daily, as clinically tolerated. Subjects were assessed during Screening and Baseline to determine eligibility for the study. Once eligible, 5 Treatment Phase visits to the clinic were required at Week 4, Week 8, Week 12, Week 15, and Week 16 (final study visit). An Early Termination (ET) Visit was conducted for subjects who discontinued prior to Week 16; all assessments planned for the final Week 16 Visit were conducted during the ET Visit, if applicable. Subjects were contacted at least weekly by telephone or email to assess tolerance to study drug, adverse events (AEs ), and changes to concomitant medications.”).</p> <p>A POSA would read each and every one of these disclosures in light of the POSA’s understanding of the relevant art. UTC’s investigation into the facts relevant to this issue is ongoing and expert discovery is in its early stages. UTC thus offers the above support without waiver of its right to rely on the knowledge of a POSA to further establish priority to Provisional Application No. 63/011,810.</p>
<b>16.</b> The method of claim 15, wherein the single inhalation administration event does not exceed 15 breaths by the patient.	<p>The disclosures cited <i>supra</i>, claims 1, 15.</p> <p>A POSA would read each and every one of these disclosures in light of the POSA’s understanding of the relevant art. UTC’s investigation into the facts relevant to this issue is ongoing and expert discovery is in its early stages. UTC thus offers the above support without waiver of its right to rely on the knowledge of a POSA to further establish priority to Provisional Application No. 63/011,810.</p>
<b>17.</b> The method of claim 1, wherein said administering increases a 6 minutes walk distance of the patient by at least 10	<p>The disclosures cited <i>supra</i>, claim 1.</p> <p>[0080] (“An exacerbation of underlying lung disease is defined as an acute, clinically significant, respiratory deterioration characterized by evidence of new widespread alveolar abnormality (Collard et al., 2016). The present example shows that treatment with inhaled</p>

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m after 8 weeks of the administering.	<p>treprostinil resulted in significantly fewer exacerbations of underlying lung disease in patients.”)</p> <p>[0081] (“Subjects having underlying lung disease were treated with inhaled treprostinil over 16 weeks. Subjects initiated inhaled treprostinil or placebo at a dose of 3 breaths (18 mcg) 4 times daily (during waking hours). Study drug doses were maximized throughout the study. Dose escalations (additional 1 breath 4 times daily) could occur up to every 3 days with a target dosing regimen of 9 breaths (54 mcg) 4 times daily and a maximum dose of 12 breaths (72 mcg) 4 times daily, as clinically tolerated. Subjects were assessed during Screening and Baseline to determine eligibility for the study. Once eligible, 5 Treatment Phase visits to the clinic were required at Week 4, Week 8, Week 12, Week 15, and Week 16 (final study visit). An Early Termination (ET) Visit was conducted for subjects who discontinued prior to Week 16; all assessments planned for the final Week 16 Visit were conducted during the ET Visit, if applicable. Subjects were contacted at least weekly by telephone or email to assess tolerance to study drug, adverse events (AEs), and changes to concomitant medications.”).</p> <p>[0082] (“Efficacy assessments consisted of 6MWD, plasma NT-proBNP concentration, and time to clinical worsening. Exploratory endpoints included SGRQ, change in DSP, time to exacerbation of underlying disease, and pulmonary function tests. Safety assessments consisted of the development of AEs, vital signs, clinical laboratory parameters, ECG parameters, hospitalizations due to cardiopulmonary indications, exacerbations of underlying lung disease, and oxygenation.”).</p> <p>[0083] (“Treatment resulted in significantly fewer exacerbations of underlying lung disease over the 16-week treatment period (26.4% in Inhaled Treprostinil group and 38.7% in placebo group; p=0.018) and decreased risk of an exacerbation of underlying lung disease (hazard ratio 0.66 or 34% reduction in risk) as shown in FIG. 1.”).</p> <p>[0084] (“In addition, the following FVC suggestive data was obtained from this study. Among patients treated with inhaled treprostinil, overall results from intent to treat group were:</p> <p>Overall ITT</p> <p>28.47 mL and 44.40 mL in FVC at Weeks 8 and 16</p>

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	<p>Percent predicted FVC at Week 8 (1.79%; p=0.0139) and Week 16 (1.80%; p=0.0277).</p> <p>Subset IIP etiology:</p> <p>46.48 mL and 108.18 mL (p=0.0229) at Weeks 8 and 16</p> <p>Percent predicted FVC at Week 8 (1.95%, p=0.0373) and Week 16 (2.88%; p=0.0096)</p> <p>Subset IPF etiology:</p> <p>84.52 mL and 168.52 mL (p=0.0108) at Weeks 8 and 16</p> <p>Percent predicted FVC at Week 8 (2.54%; p=0.0380) and Week 16 (3.50%; p=0.0147)</p> <p>Nintedanib: IPF - 109 mL (3.2% predicted) at 52 weeks</p> <p>Pirfenidone: IPF - 153-193 mL at 52 weeks</p> <p>Placebo corrected, rate of decline (not improvements)</p> <p>In comparison to the known treatments for ILD (nintedanib and pirfenidone) shown above, inhaled treprostinil achieves comparable effects with shorter treatment duration.”).</p> <p>[0085] (“Pulmonary function testing was initially conducted as a safety assessment (Safety Population) during the study. The results indicated that although most PFT parameters remained stable for subjects in the study, a notable improvement in FVC (% predicted) was observed at Week 16 in the inhaled treprostinil group (median improvement of 1.0% compared to a 1.0% reduction in the placebo group). As a result, post hoc MMRM analyses of FVC data were performed for the ITT Population and are presented in Table 1 (ITT Population), Table 2 (by PH ILD Etiology of IIP) and Table 3 (for subjects with IPF), shown below.”).</p> <p><b>Table 1</b> [see Claim 1, above.]</p> <p><b>Table 2</b> [see Claim 1, above.]</p> <p><b>Table 3</b> [see Claim 1, above.]</p>

Asserted '327 Patent Claim	Support Found in Provisional Application No. 63/011,810
	<p>[0086] (“Treatment with inhaled treprostinil resulted in improvements of 28.47 mL and 44.40 mL in FVC at Weeks 8 and 16, respectively; significant when presented as% predicted FVC at Week 8 (1.79%; p=0.0139) and Week 16 (1.80%; p=0.0277).”).</p> <p>[0087] (“When FVC was analyzed by PH-ILD etiology of IIP, treatment with inhaled treprostinil resulted in improvements of 46.48 mL and 108.18 mL (p=0.0229) when compared to placebo at Weeks 8 and 16, respectively. The between group differences for% predicted FVC were statistically significant at Week 8 (1.95%, p=0.0373) and Week 16 (2.88%; p=0.0096).”).</p> <p>[0088] (“Further analysis of FVC for subjects with an IPF etiology (using only the IIP subjects in the ITT Population), showed that treatment with inhaled treprostinil resulted in improvements of 84.52 mL and 168.52 mL (p=0.0108) compared to placebo at Weeks 8 and 16, respectively. The between group differences for% predicted FVC were statistically significant at Week 8 (2.54%; p=0.0380) and Week 16 (3.50%; p=0.0147).”).</p> <p>A POSA would read each and every one of these disclosures in light of the POSA’s understanding of the relevant art. UTC’s investigation into the facts relevant to this issue is ongoing and expert discovery is in its early stages. UTC thus offers the above support without waiver of its right to rely on the knowledge of a POSA to further establish priority to Provisional Application No. 63/011,810.</p>
<p><b>18.</b> The method of claim 1, wherein said administering increases a 6 minutes walk distance of the patient by at least 15 m after 12 weeks of the administering.</p>	<p>The disclosures cited <i>supra</i>, claim 1.</p> <p>[0080] (“An exacerbation of underlying lung disease is defined as an acute, clinically significant, respiratory deterioration characterized by evidence of new widespread alveolar abnormality (Collard et al., 2016). The present example shows that treatment with inhaled treprostinil resulted in significantly fewer exacerbations of underlying lung disease in patients.”).</p> <p>[0081] (“Subjects having underlying lung disease were treated with inhaled treprostinil over 16 weeks. Subjects initiated inhaled treprostinil or placebo at a dose of 3 breaths (18 mcg) 4 times daily (during waking hours). Study drug doses were maximized throughout the study. Dose escalations (additional 1 breath 4 times daily) could occur up to every 3 days with a target dosing regimen of 9 breaths (54 mcg) 4 times daily and a maximum dose of 12 breaths (72 mcg) 4 times daily, as clinically tolerated. Subjects were assessed during Screening and Baseline to determine eligibility for the study. Once</p>

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	<p>eligible, 5 Treatment Phase visits to the clinic were required at Week 4, Week 8, Week 12, Week 15, and Week 16 (final study visit). An Early Termination (ET) Visit was conducted for subjects who discontinued prior to Week 16; all assessments planned for the final Week 16 Visit were conducted during the ET Visit, if applicable. Subjects were contacted at least weekly by telephone or email to assess tolerance to study drug, adverse events (AEs ), and changes to concomitant medications.”).</p> <p>[0082] (“Efficacy assessments consisted of 6MWD, plasma NT-proBNP concentration, and time to clinical worsening. Exploratory endpoints included SGRQ, change in DSP, time to exacerbation of underlying disease, and pulmonary function tests. Safety assessments consisted of the development of AEs, vital signs, clinical laboratory parameters, ECG parameters, hospitalizations due to cardiopulmonary indications, exacerbations of underlying lung disease, and oxygenation.”).</p> <p>[0083] (“Treatment resulted in significantly fewer exacerbations of underlying lung disease over the 16-week treatment period (26.4% in Inhaled Treprostинil group and 38.7% in placebo group; p=0.018) and decreased risk of an exacerbation of underlying lung disease (hazard ratio 0.66 or 34% reduction in risk) as shown in FIG. 1.”).</p> <p>[0084] (“In addition, the following FVC suggestive data was obtained from this study. Among patients treated with inhaled treprostинil, overall results from intent to treat group were:</p> <p>Overall ITT</p> <p>28.47 mL and 44.40 mL in FVC at Weeks 8 and 16</p> <p>Percent predicted FVC at Week 8 (1.79%; p=0.0139) and Week 16 (1.80%; p=0.0277).</p> <p>Subset IIP etiology:</p> <p>46.48 mL and 108.18 mL (p=0.0229) at Weeks 8 and 16</p> <p>Percent predicted FVC at Week 8 (1.95%, p=0.0373) and Week 16 (2.88%; p=0.0096)</p> <p>Subset IPF etiology:</p>

Asserted '327 Patent Claim	Support Found in Provisional Application No. 63/011,810
	<p>84.52 mL and 168.52 mL (<math>p=0.0108</math>) at Weeks 8 and 16</p> <p>Percent predicted FVC at Week 8 (2.54%; <math>p=0.0380</math>) and Week 16 (3.50%; <math>p=0.0147</math>)</p> <p>Nintedanib: IPF - 109 mL (3.2% predicted) at 52 weeks</p> <p>Pirfenidone: IPF - 153-193 mL at 52 weeks</p> <p>Placebo corrected, rate of decline (not improvements)</p> <p>In comparison to the known treatments for ILD (nintedanib and pirfenidone) shown above, inhaled treprostinil achieves comparable effects with shorter treatment duration.”).</p> <p>[0085] (“Pulmonary function testing was initially conducted as a safety assessment (Safety Population) during the study. The results indicated that although most PFT parameters remained stable for subjects in the study, a notable improvement in FVC (% predicted) was observed at Week 16 in the inhaled treprostinil group (median improvement of 1.0% compared to a 1.0% reduction in the placebo group). As a result, post hoc MMRM analyses of FVC data were performed for the ITT Population and are presented in Table 1 (ITT Population), Table 2 (by PH ILD Etiology of IIP) and Table 3 (for subjects with IPF), shown below.”).</p> <p><b>Table 1</b> [<i>see</i> Claim 1, above.]</p> <p><b>Table 2</b> [<i>see</i> Claim 1, above.]</p> <p><b>Table 3</b> [<i>see</i> Claim 1, above.]</p> <p>[0086] (“Treatment with inhaled treprostinil resulted in improvements of 28.47 mL and 44.40 mL in FVC at Weeks 8 and 16, respectively; significant when presented as % predicted FVC at Week 8 (1.79%; <math>p=0.0139</math>) and Week 16 (1.80%; <math>p=0.0277</math>).”).</p> <p>[0087] (“When FVC was analyzed by PH-ILD etiology of IIP, treatment with inhaled treprostinil resulted in improvements of 46.48 mL and 108.18 mL (<math>p=0.0229</math>) when compared to placebo at Weeks 8 and 16, respectively. The between group differences for % predicted FVC were statistically significant at Week 8 (1.95%, <math>p=0.0373</math>) and Week 16 (2.88%; <math>p=0.0096</math>).”).</p>

Asserted '327 Patent Claim	Support Found in Provisional Application No. 63/011,810
	<p>[0088] (“Further analysis of FVC for subjects with an IPF etiology (using only the IIP subjects in the ITT Population), showed that treatment with inhaled treprostinil resulted in improvements of 84.52 mL and 168.52 mL (p=0.0108) compared to placebo at Weeks 8 and 16, respectively. The between group differences for% predicted FVC were statistically significant at Week 8 (2.54%; p=0.0380) and Week 16 (3.50%; p=0.0147).”).</p> <p>A POSA would read each and every one of these disclosures in light of the POSA’s understanding of the relevant art. UTC’s investigation into the facts relevant to this issue is ongoing and expert discovery is in its early stages. UTC thus offers the above support without waiver of its right to rely on the knowledge of a POSA to further establish priority to Provisional Application No. 63/011,810.</p>
<p><b>19.</b> The method of claim 1, wherein said administering increases a 6 minutes walk distance of the patient by at least 15 m after 16 weeks of the administering.</p>	<p>The disclosures cited <i>supra</i>, claim 1.</p> <p>[0080] (“An exacerbation of underlying lung disease is defined as an acute, clinically significant, respiratory deterioration characterized by evidence of new widespread alveolar abnormality (Collard et al., 2016). The present example shows that treatment with inhaled treprostinil resulted in significantly fewer exacerbations of underlying lung disease in patients.”).</p> <p>[0081] (“Subjects having underlying lung disease were treated with inhaled treprostinil over 16 weeks. Subjects initiated inhaled treprostinil or placebo at a dose of 3 breaths (18 mcg) 4 times daily (during waking hours). Study drug doses were maximized throughout the study. Dose escalations (additional 1 breath 4 times daily) could occur up to every 3 days with a target dosing regimen of 9 breaths (54 mcg) 4 times daily and a maximum dose of 12 breaths (72 mcg) 4 times daily, as clinically tolerated. Subjects were assessed during Screening and Baseline to determine eligibility for the study. Once eligible, 5 Treatment Phase visits to the clinic were required at Week 4, Week 8, Week 12, Week 15, and Week 16 (final study visit). An Early Termination (ET) Visit was conducted for subjects who discontinued prior to Week 16; all assessments planned for the final Week 16 Visit were conducted during the ET Visit, if applicable. Subjects were contacted at least weekly by telephone or email to assess tolerance to study drug, adverse events (AEs ), and changes to concomitant medications.”).</p> <p>[0082] (“Efficacy assessments consisted of 6MWD, plasma NT-proBNP concentration, and time to clinical worsening. Exploratory endpoints included SGRQ, change in DSP, time to exacerbation of</p>

Asserted '327 Patent Claim	Support Found in Provisional Application No. 63/011,810
	<p>underlying disease, and pulmonary function tests. Safety assessments consisted of the development of AEs, vital signs, clinical laboratory parameters, ECG parameters, hospitalizations due to cardiopulmonary indications, exacerbations of underlying lung disease, and oxygenation.”).</p> <p>[0083] (“Treatment resulted in significantly fewer exacerbations of underlying lung disease over the 16-week treatment period (26.4% in Inhaled Treprostinil group and 38.7% in placebo group; p=0.018) and decreased risk of an exacerbation of underlying lung disease (hazard ratio 0.66 or 34% reduction in risk) as shown in FIG. 1.”).</p> <p>[0084] (“In addition, the following FVC suggestive data was obtained from this study. Among patients treated with inhaled treprostinil, overall results from intent to treat group were:</p> <p>Overall ITT</p> <p>28.47 mL and 44.40 mL in FVC at Weeks 8 and 16</p> <p>Percent predicted FVC at Week 8 (1.79%; p=0.0139) and Week 16 (1.80%; p=0.0277).</p> <p>Subset IIP etiology:</p> <p>46.48 mL and 108.18 mL (p=0.0229) at Weeks 8 and 16</p> <p>Percent predicted FVC at Week 8 (1.95%, p=0.0373) and Week 16 (2.88%; p=0.0096)</p> <p>Subset IPF etiology:</p> <p>84.52 mL and 168.52 mL (p=0.0108) at Weeks 8 and 16</p> <p>Percent predicted FVC at Week 8 (2.54%; p=0.0380) and Week 16 (3.50%; p=0.0147)</p> <p>Nintedanib: IPF - 109 mL (3.2% predicted) at 52 weeks</p> <p>Pirfenidone: IPF - 153-193 mL at 52 weeks</p> <p>Placebo corrected, rate of decline (not improvements)</p>

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	<p>In comparison to the known treatments for ILD (nintedanib and pirfenidone) shown above, inhaled treprostinil achieves comparable effects with shorter treatment duration.”).</p> <p>[0085] (“Pulmonary function testing was initially conducted as a safety assessment (Safety Population) during the study. The results indicated that although most PFT parameters remained stable for subjects in the study, a notable improvement in FVC (% predicted) was observed at Week 16 in the inhaled treprostinil group (median improvement of 1.0% compared to a 1.0% reduction in the placebo group). As a result, post hoc MMRM analyses of FVC data were performed for the ITT Population and are presented in Table 1 (ITT Population), Table 2 (by PH ILD Etiology of IIP) and Table 3 (for subjects with IPF), shown below.”).</p> <p><b>Table 1</b> [see Claim 1, above.]</p> <p><b>Table 2</b> [see Claim 1, above.]</p> <p><b>Table 3</b> [see Claim 1, above.]</p> <p>[0086] (“Treatment with inhaled treprostinil resulted in improvements of 28.47 mL and 44.40 mL in FVC at Weeks 8 and 16, respectively; significant when presented as % predicted FVC at Week 8 (1.79%; p=0.0139) and Week 16 (1.80%; p=0.0277).”).</p> <p>[0087] (“When FVC was analyzed by PH-ILD etiology of IIP, treatment with inhaled treprostinil resulted in improvements of 46.48 mL and 108.18 mL (p=0.0229) when compared to placebo at Weeks 8 and 16, respectively. The between group differences for % predicted FVC were statistically significant at Week 8 (1.95%, p=0.0373) and Week 16 (2.88%; p=0.0096).”).</p> <p>[0088] (“Further analysis of FVC for subjects with an IPF etiology (using only the IIP subjects in the ITT Population), showed that treatment with inhaled treprostinil resulted in improvements of 84.52 mL and 168.52 mL (p=0.0108) compared to placebo at Weeks 8 and 16, respectively. The between group differences for % predicted FVC were statistically significant at Week 8 (2.54%; p=0.0380) and Week 16 (3.50%; p=0.0147).”).</p> <p>A POSA would read each and every one of these disclosures in light of the POSA’s understanding of the relevant art. UTC’s investigation into the facts relevant to this issue is ongoing and expert discovery is</p>

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	in its early stages. UTC thus offers the above support without waiver of its right to rely on the knowledge of a POSA to further establish priority to Provisional Application No. 63/011,810.

Discovery and UTC's investigation into facts relevant to this case is ongoing, and UTC expressly reserves the right to amend and/or supplement its answer to this Interrogatory as discovery and the case continues.

**INTERROGATORY NO. 6:**

Describe in detail each category of relief (including, without limitation, any monetary, punitive, or injunctive relief) that UTC seeks, including the facts evidencing or supporting any such relief, for Liquidia's alleged infringement of the Asserted Claims, including but not limited to, the nature and amount of any damages, and time period of accrual for each category of damages. A complete response must include the proposed length of time of any injunction sought and describe, with specificity and not by reference to the First Amended Complaint or any other document, the act or acts sought to be enjoined or restrained, as required under Rule 65 of the Federal Rules of Civil Procedure.

**RESPONSE TO INTERROGATORY NO. 6 (6/5/2024):**

UTC incorporates the Preliminary Statement, General Objections, Objections to Definitions, and Objections to Instructions by reference as if stated herein. UTC further objects as fact discovery in this case is ongoing, document production is not complete, expert discovery has not yet begun, and the Court has not yet construed any claim terms. UTC objects to this Interrogatory as premature as seeks expert opinions. UTC further objects to the extent this Interrogatory calls for legal conclusions. UTC objects to this Interrogatory to the extent it comprises multiple subparts so as to comprise multiple distinct interrogatories and is not properly propounded as a single interrogatory. UTC objects to this Interrogatory to the extent it calls for information protected by attorney-client privilege, the work-product doctrine, or any other applicable privilege or immunity. UTC objects to this Interrogatory as overbroad, unduly burdensome, and not proportional to the needs of the case, including for demanding a response "in

Liquidia has improperly withheld, without basis, documents and witness testimony related to the commercial aspects of its accused Yutrepia product (e.g., financial data, forecasts, launch plans, etc.). UTC has explained repeatedly that this discovery is highly relevant to UTC's damages claims in this case. *See, e.g.*, D.I. 180 at 3-4; Email from K. Pappas to R. Minn et al. (Oct. 3, 2024 at 5:00 PM ET); Email from K. Pappas to R. Preston et al (Oct. 8, 2024 1:08 AM ET); Email from J. Vallen to R. Minn et al. (Oct. 8, 2024 10:56 AM ET); Email from A. Dykhuis to R. Preston et al. (Oct. 8, 2024); Email from J. Vallen to R. Minn et al. (Oct. 14, 2024 at 11:56 PM ET); Letter from W. Jackson to Liquidia Counsel (Oct. 14, 2024); Email from S. McDermott to R. Preston et al. (Nov. 1, 2024 at 10:01 AM ET); Email from B. Ediger to R. Preston et al. (Nov. 2, 2024 at 8:18 PM ET). The Court granted UTC's motion to compel, ordering production by Liquidia not later than November 19, 2024. *See* D.I. 193. After Liquidia provides this and other improperly withheld discovery, UTC reserves the right to supplement its response to this Interrogatory.

Discovery and UTC's investigation into facts relevant to this case is ongoing, and UTC expressly reserves the right to amend and/or supplement its answer to this Interrogatory as discovery and the case continues.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Michael J. Flynn*

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November 19, 2024

**CERTIFICATE OF SERVICE**

I hereby certify that on November 19, 2024, copies of the foregoing were caused to be served upon the following in the manner indicated:

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